Evaluation of Multi-Drug Resistant Tuberculosis Treatment Services' Quality in St, Peter Specialized Hospital Addis Ababa, Ethiopia

An Evaluation report to be submitted to

Jimma University, Institute of Health; Department of Health Policy and Management; Monitoring and Evaluation Post Graduate Program Coordinating Unit For partial fulfillment of Degree of Masters in Health Monitoring and Evaluation

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Evaluation of Multi-Drug Resistant Tuberculosis Treatment Services' Quality in St, Peter specialized hospital Addis Ababa, Ethiopia

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Thesis declaration form

I, the undersigned, hereby declare that this thesis is my original work. The work has not been presented for degree in any university and source of materials used for the project has been acknowledged.

Thesis title: Evaluation of Multi-Drug Resistant Tuberculosis Treatment services Quality in Saint Peter Specialized Hospital, Addis Ababa , Ethiopia.

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Abstract

Background; -. *The emergence of drug-resistant tuberculosis is currently a challenge for the End-TB strategy. Globally in 2018 alone, there were about three hundred ninety thousand new cases of Multidrug-resistant tuberculosis (MDR-TB The MDR-TB treatment success rate of St. Peter Specialized Hospital is in a decreasing pattern. Furthermore , Delay to initiate the chemotherapy after diagnosis is noticed. However, the reason is not assessed from a holistic perspective yet.*

Objective*; - To assess the quality of Multi-Drug Resistant Tuberculosis treatment service in St. Peter specialized hospital, Ethiopia, 2020.*

Methods and Materials*; - The formative evaluation was conducted from April 1to April 21 2020 by applying the Donabedian framework for quality assessment in St. Peter specialized hospital. A single case study design was selected. It was assessed based on availability, compliance, Interim clinical outcome, and satisfaction dimensions. Moreover, twenty provider-patient interactions observation, thirteen Key informant interviews, and all patient charts for the last two years reviewed, and all patients currently on treatment were interviewed. The inventory and chart review checklists were taken from the national guideline. The observation and interview tools were adapted from different literatures. Thematic analysis technique was applied for the qualitative data. And for the quantitate data, Descriptive summary and principal component analysis were done by SPSS 25.*

Result: - *The evaluation finding indicate resource availability scores of 77.7%. The absence of culture laboratory, shortage of training for the staff were the identified gaps. And interrupted supply of plumpy-nut and chemistry test reagents were the uncovered problem. The compliance score was 68%. Baseline and follow up physical examinations were done only for less than half(48.5%) of the patients. Only 31.4% of patients had a second-line drug sensitivity test. There was no supportive supervision in the last six months. The social support covers 65% of the eligible clients. The interim clinical outcome scores 88%. Whereas, the overall satisfaction score with multidrug-resistant TB is 75.6%. The overall quality based on the judgment parameter was good.*

Conclusion and Recommendation*: - Interruptions of Ready To use therapeutic food supply, laboratory reagent should be managed by the hospital. The culture laboratory should be finished. Provision of social support, on-job training and supportive supervision with written timely feedback should be improved by the Ministry of Health.*

Key Words*: - TB, MDR-TB, Drug-resistant TB, St. Peter specialized hospital*

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Table of Contents

Abstract iii
Acknowledgment v
List of Tables viii
List of Figures ix
Acronyms and Abbreviations x
Operational Definitions xi
Chapter One: Introduction 1
1.1. Background 1
1.2 Statement of the Problem 3
1.3. Significance of the Evaluation 5
Chapter Two: Program Description of National Programmatic Management of Drug-resistant Tuberculosis in Ethiopia 6
2.1 Stakeholders Engagement 6
2.3. Goal 9
2.4. General objectives 9
2.4.1 Specific objectives 9
2.5. Major strategies 9
Program resources and activities 10
2.7 Logic model 12
2.8. History and Stage of Development 14
Chapter Three: Literature Review- 15
3.1. Availability 15
3.2 Compliance 16
Chapter Four: Evaluation Questions and Objectives 19
4.1. Evaluation Questions 19
4.2 General Objective 19
4.2.1 Specific Objectives 19
Chapter Five: Evaluation Methods 20
5.1. Study Area and period 20
5.5. Dimensions of the Evaluation 21
5.6.1 Indicators 21
5.6.1.1 (Input) Availability Resources 21
5.6.1.2- (Process) Compliance of the service provider to the national MDR-TB treatment protocol 22

5.6.1.3(Immediate Outcome) Acceptability/Satisfaction; - 23
5.6.1.4 (Intermediate Outcome) Clinical outcome; - 24
5.7. Sample size and sampling technique 24
Sample size for observation: 24
5.8. Study unit and unit of analysis 25
5.9. Unit of Analysis 25
5.10. Inclusion and exclusion criteria 25
5.11 Data Collection method and tool 25
5.11.2 Data collection Procedure 25
5.11.3. Data collectors 26
5.12 Data analysis 26
5.14 Data quality management 27
5.15. Judgment parameter and matrix of analysis 28
5.16 Ethical consideration 28
5.17 Dissemination plan 28
Chapter Six: Results 29
6.1 Availability of resources 29
6.1.1 Human Resources 29
6.1.3 Laboratory service availability 32
6.2 Compliance of health care professionals to the guideline 35
6.2.1 Communication with patients 35
6.2.2 Physical examinations 36
6.2.3 Laboratory investigations 37
6.2.5 Regarding Drug adherence 39
6.3 Interim Clinical Outcome 42
6.4 Patient Satisfaction with the MDR-TB treatment Services 43
Chapter Seven: Discussion 48
7.1 Availability of Resources 48
7.2 Compliance of the healthcare professionals to the national treatment guideline 49
7.3 Interim clinical Outcome of the patients 51
7.4 Satisfaction of MDR-TB patients on MDR-TB treatment Services 51
Limitation of the study 51
Chapter Eight: Conclusion and Recommendations 52
8.1 Conclusion 52
8.2 Recommendations 52

Chapter Nine: Meta-Evaluation **54**
Utility standards **54**
Feasibility standards **54**
Propriety Standards **54**
Accuracy standards **54**
References **55**
Annexes **60**
Annex 1: Information matrixes **60**
Annex 2: Relevance matrix of indicators **69**
Annex 4: Data collection tools **72**
Annex 5: Meta-Evaluation Judgement checklist **87**
Annex 6 The principal component analysis Results **93**

List of Tables

Table 1: Stakeholder matrix of MDR-TB treatment program evaluation in St. Peter specialized hospital 2020. 6
Table 2 The number of available MDR-TB case team staff professions compared with the NTG in SPSH Addis Ababa Ethiopia, 2020 29
Table 3 The core MDR-TB drug inventory of the SPSH Addis Ababa, Ethiopia 2020 31
Table 4 The availability of necessary laboratory tests and equipment in SPSH, Addis Ababa, Ethiopia 2020 32
Table 5 Judgment parameter for the availability of necessary resource and equipment for MDR-TB treatment service in SPSH Addis Ababa Ethiopia, 2020 34
Table 6 Description of the patient's demography and MDR-TB clinical conditions in St peter specialized hospital, Addis Ababa, Ethiopia 2020. 35
Table 7 Baseline and follow up bacteriological test s of ST peter specialized hospital MDR-TB patients Addis Ababa, Ethiopia,2020 38
Table 8 Judgment matrix for compliance of MDR-TB DOT PLUS services providers to NTG in SPSH, Addis Ababa, 2020. 41
Table 9 The clinical outcome of 61 MDR-TB patients who finished the treatment reviewed in SPSH, Addis Ababa, Ethiopia 2020 42

Table 10 judgment matrix of interim clinical outcome of MDR-TB patients in SPSH, Addis Ababa, Ethiopia 2020..... 43
Table 11 shows the Socio-demographic characteristics of MDR-TB patients in SPSH Addis Ababa, Ethiopia 2020..... 44
Table 12 shows the general characteristics of MDR-TB patients in SPSH Addis Ababa, Ethiopia 2020..... 45
Table 13 the Judgment Matrix for Satisfaction of MDR-TB patients' acceptability of treatment service in SPSH, A.A Ethiopia 2020 46
Table 14 Overall judgment matrixes and analysis of dimension of MDR-TB treatment services in SPSH, Addis Ababa, Ethiopia 2020. 47
Table 15: Information matrix for the availability of the necessary resource in St. Peter specialized hospital Addis Ababa 60
Table 16: Information matrix for compliance TB DOT PLUS service providers to national TB guideline in St. Peter specialized hospital..... 62
Table 17 Information Matrix for the satisfaction of patients from MDR-TB Treatment service in St. Peter specialized hospital Addis Ababa..... 66
Table 18: information Matrix of MDR-TB treatment Outcome of St. Peter specialized hospital Addis Ababa, 2020..... 68
Table 19:Relevance matrix of indicators that was used in quality evaluation in St. Peter specialized hospital,2020 69
Table 20: Patient Satisfaction Questions 75

List of Figures

Figure 1, The Logic model of MDR-TB treatment service in SPSH Addis Ababa,2020..... 13
Figure 2 conceptual framework adapted from A quality assessment done in private clinics of Addis Ababa (58) of evaluation of MDR-TB treatment services Quality in St. Peter specialized hospital, Addis Ababa, Ethiopia,2020 18
Figure 3 Baseline physical examinations done for 132 patients in SPSH Addis Ababa, Ethiopia 2020..... 36
Figure 4 Follow up physical examinations done for 132 patients in SPSH, Addis Ababa, 2020.37

Acronyms and Abbreviations

AIDS……Acquired Immune Deficiency Syndrome

AAHB…….…… Addis Ababa Health Bureau

BCC…… Behavioral Change Communication

DOT…… Directly Observed Therapy

DST……. Drug Sensitivity Test

EA……Evaluability Assessment

EPHI…….Ethiopian Public Health Institute

FMOH…….Federal Ministry of Health

GHC…… Global Health Committee

HIV……. Human Immunodeficiency Virus

HSTP……Health Sector Transformation Plan

IEC……... Information, Education, and Communication

MDR TB…… Multi-Drug Resistance Tuberculosis

MDG……Millennium Development Goals

SOP…….Standard Operating Procedure

NTLCP……National Tuberculosis and Leprosy Control Program

PPE……. Personal Protective Equipment

SLD……. Second-line Drugs

LPA……... Line Probe Assay

NTG……...National Treatment Guideline

SL-LPA…… Second line- Line Probe Assay

SPSH……St. Peter Specialized Hospital

TIC……Treatment initiation Center

TFC……Treatment follow up Center

WHO……World Health Organization

XDR-TB…… Extensive Drug-Resistant Tuberculosis

Operational Definitions

Adequate counseling: In this evaluation, Information communication between care provider and patient the transfer of the information regarding TB and its treatment. Includes explanations of how MDR-TB transmitted, how to take the drug and its possible side effect, an advantage of DOT Plus, advise the patient to bring any family member or neighborhood having signed and symptoms of TB to the health facility.

Availability: In this evaluation, It is the presence of infrastructures (MDR-TB ward, cough clinic, MDR-TB OPD, water, electricity), laboratory equipment (Microscopy, Gene expert machine, chemistry, CD4 machine, HCG, HIV, Hepatitis kit, X-ray machine, ECG), recording and recording materials (MDR-TB registers, report formats, individual card), Human resources and MDR-TB guidelines as per the MDR-TB treatment guideline.

Baseline laboratory examinations;- means the laboratory examinations done for the patient at the time of diagnosis

Baseline/follow up physical examinations;- In this study, baseline/ follow up physical examinations include vital signs, Audiometry, visual acuity and color test and Peripheral neuropathy screening.

Baseline Blood tests;- In this study, the baseline blood tests include CBC (complete blood count), BUN (Urea, creatinine), serum electrolytes, liver function test (LFT), TSH (Thyroid Stimulating Hormone), (HBA) Hepatitis B antibody / (HCA) Hepatitis C Antibody), FBS (Fasting Blood Sugar).

Compliance: In this evaluation, it is the provision of therapeutic services(start SLDs promptly, follow up of adverse events during therapy, Nutritional management, provide social support,)after the diagnosis is confirmed based on national guideline recommendations.

Conversion: In this evaluation, it is described as the sample taken from the bacteriologically con two samples of successive negative culture and smear, from the samples taken a month separately.

Follow up Blood tests;- In this study, follow up blood tests include CBC, BUN,serum electrolytes, LFT, and TSH.

Full-time trained DOT PLUS provider: is a responsible trained staff permanently assigned (at least basic 5 working hours of days DOT PLUS training) available at work time in TB unit.

Gene expert with all essential equipment;- means Gene Xpert the instrument and the computer, cartridges, Assay specific Gene Xpert cartridges, Printer, Surge protector(, triple package container.

Interim Clinical Outcome;- In this evaluation, it is the clinical outcome of bacteriologically confirmed MDR-TB patients after four to six months of treatment.

Microscopy with essential equipment;- means Functional Binocular light Microscopes, Slide, Frosted slide, Slide box, Sputum containers approved, Wire loops or sticks, Funnel, Filter paper, Staining rack, Sprit lamp/Bunsen burner, Lens tissue, Red pen Recording for positive result, Carbol fuchsine, Methyl blue 52 3% acid alcohol, Oil immersion, Forceps for holding slide and fixing, Alarm clock 56 5% phenol or 10% Sodium hypo chloride.

Necessary SLDs:- In this study, the necessary SLDs includes Bedaquiline (Bdq), Levofloxacin (Lfx), Moxifloxacin (Mx),Linezolid (Lzd) , Clofazimine (Cfz), Cycloserine (Cs),Amikacin (Amk),Delamanid (Dlm), Protionamide (Pto) or Ethionamide (Eto).

Out of stock;- If a drug or a reagent is not available for a single day, that drug or a reagent considered as out of stock.

Patient Satisfaction score: In this evaluation, patient's perceived opinion about the care received from MDR-TB unit staffs. It was measured with 5-point Likert score. Then it was translated into percentage by using standardized mean scale score formula.

Routine;- means the physical and laboratory tests done for the patient at follow up visits.

Standard MDR-TB unit: separate TB unit/room with good ventilation which has isolated waiting area for MDR-TB DOT PLUS patients.

Standardized PPE (Personal Protective Equipment);- In this study PPE include PPE includes N-95 or PPF masks for the HPs and clients, gloves for health care professionals.

Trained Staff;- Based on the national guideline, all health professionals working in MDR-TB unit must get the MDR-TB training. Therefore, all staffs of SPSH are expected to be trained.

Well ventilated; - In this evaluation, wind-driven roof turbines in a room called well ventilated.

Chapter One: Introduction

1.1. Background

Quality in health care has different definitions from different scholars. However, the main objective of ensuring quality of health service is to increase the better health outcome.(Donabedian, 2003; Making, Choices and Systems, 2006). Having a better clinical outcome in MDR-TB therapy, is crucial not only for the patient but also as the prevention for the community as a whole(PMDTB (FMOH), 2019).

MDR(Multi-Drug Resistant Tuberculosis) strain of TB(Tuberculosis) evolving as the international public health problem. The reason behind this is, it has greater ill-health and mortality than a drug-sensitive strain of TB (4,5). Across the globe in 2018 alone, 390,000 new cases of drug-resistant TB were diagnosed. From new cases, 3.4%, and from previously treated cases 18%, had MDR-TB or TB. Furthermore, the global success rate for the MDR-TB is though increasing is only 56% by 2018 (6).

It is also the main cause of death due to antimicrobial resistance(6). MDR TB is triggered by a bacterium called Mycobacterium Tuberculosis which is resistant to a minimum of isoniazid and rifampin, the two potent first-line TB medications (3).

The catastrophic cost faced by MDR-TB patients and their households for treating drug-resistant TB across the globe is from 67% up to 100%. Despite different efforts made to make the SLD (Second-line drugs) treatment accessible, only one in three MDR-TB patients getting the treatment service across the world(7,8).

In Africa, due to scarcity of diagnostic laboratories that can perform DST (Drug Sensitivity Test) tests only 51% and 72% from new and previously treated cases get DST tests respectively (7,8). The catastrophic cost expenditure of patients and their caretakers is another challenge in the continent(9).

Since Ethiopia cannot perform universal DST for all TB cases, the performance for the early diagnosis and treatment for drug-resistant TB is severely halted and makes it difficult to know the actual incidence (10,11). The success rate of MDR-TB is 72%. This MDR-TB success rate may be higher than the Global and across continent success rate. However, it is significantly lower as compared to the target which was 82%(8,10).

A very complex treatment procedure is undergoing the treatment of MDR-TB. It takes from 18-24 months. Since 2013, there is also a short regimen (9 to 11 months) recommended by WHO(World Health Organization) and NTG(National Treatment Guideline) guidelines (3,13). It also usually leaves a longstanding complication that affects the physical and social aspects of a patient's life. Due to the disease, the patient's organs may endure physical and functional sequels even after the patient is cured or complete the treatment (14,15).

Low quality of service is related to high mortality due to MDR-TB. Furthermore, poor quality equivalently is an obstacle for mortality reduction with treatment access (16,17). High pill load, repeated stock out of drugs, high rates of adverse events of SLDs(second-line drugs), and insufficient socioeconomic care are the quality issues that challenged the MDR-TB treatment service(18,19).

There are different challenges of MDR-TB detection and treatment service that can be classified into three categories. The first one is program-related factors. It includes absence or presence of inappropriate guidelines, scarcity of Rapid DST diagnostic equipment, failure to comply as per the guideline. The second challenge is Drug-related factors. It includes scarcity, poor quality, wrong doses, or a combination of SLDs. The third challenge is patient-related factors. This involves poor adherence, substance abuse, lack of money for transportation to the health institutions are some of the patient-related factors(3).

Currently, DST is done for all suspected MDR-TB cases across the country (8,12). By converging with the Millennium Development Goals (MDG) goals and STOP TB strategy, the prevalence, and mortality of TB was able to decrease 50% from the 1990s. Then, by adopting the "END TB" strategy and integrating with the nation's Health Sector Transformation Plan (HSTP), planned to end TB by decreasing TB induced mortality by 95% and incidence 90% from the 2015 level (10). Since 2016, 46 TICs (Treatment Initiation Center) are giving the service across the nation. Also, 700 patients enrolled in the MDR-TB treatment protocol. Overall, starting from 2009 until mid of 2017 2,200 MDR-patients were enrolled in the treatment (10).

1.2 Statement of the Problem

One of the results of the compromised TB care quality is the occurrence of Drug-resistant TB. Delayed diagnosis treatment of MDR-TB patients, the initiation of treatment without confirming the diagnosis with DST, wrong regimen, and dosage are the other problems related to MDR-TB treatment service quality. Additionally, lack of empathy for the parallel social provision for the patients to facilitate for completion of chemotherapy is the major cause for the MDR-TB(18,20).

Ethiopia is among the 20 high TB burden countries in the world. New and relapse cases of 165,000 and 27,000 TB deaths occurred only by the year 2018. The incidence of MDR TB is 1.6 per thousand. The same report indicates that 0.71% are from new, 16% are from previously treated cases(21). The MDR TB prevalence differs in different parts of Ethiopia. It is 31.4% in Jimma (22) and 5% in Gonder(23). The prevalence of MDR-TB in Addis Ababa is 34%(24). In Addis Ababa, the prevalence is higher than in other regions of the nation. Furthermore, Addis Ababa is under rapid urbanization due to immigrants from different parts of the country. This produces an overcrowding residential area. This creates a fertile ground for transmission of the Drug-resistant strain of TB(25).

MDR-TB is attacking mostly the productive segment of the population. This could seriously jeopardize the economy of Ethiopia(26). Moreover, the medications that are used to treat MDR-TB are costlier and have more adverse effects. Hepatotoxicity, renal insufficiency, Hypothyroidism, and Electrocardiography (ECG), abnormality are some of the SLD side effects observed(10,13).

Moreover, the psychological complications of MDR-TB even after successful treatment includes social isolation, inability to work due to loss of identity and stigma(27). Due to the shortage of resources to treat MDR-TB, and prompt transmission of the strain makes it difficult to control the disease. Especially in sub-Saharan region countries like Ethiopia. Furthermore, the emergence and fast spread of XDR-TB (Extensive Drug-Resistant Tuberculosis) is an additional Encounter for the prevention and control program of TB(24).

The vulnerable groups for this disease are the poor, malnourished, and destitute. And those who live in overcrowded environments and without access to health institutions(28). Lack of compliance with the NTG with the treatment regimen of drug-susceptible TB is the main reason for MDR TB occurrence(5). This is also considered the key barrier to the control of TB(29). Furthermore, the notification rate achieved for MDR-TB is less than 33% as compared with the target(10).

DOT (Directly Observed Therapy) Plus program was started 11 years ago as a centralized inpatient treatment program. The reason was due to the emergence of MDR-TB disease(30). This created a problem of accessibility and adherence to the treatment. Consequently, the MDR TB treatment started a short regimen and ambulatory treatment service by the year 2013(3). As far as the evaluator's knowledge, there is a scarcity of literature that assesses the quality of new service modalities in Ethiopia. This program is resource-intensive. it costs 260$ per patient for medication alone(31). A few pilot assessments done on ambulatory care have been successful. So, now it is included in NTG. There is a gap in assessing both the inpatient and ambulatory care quality assessment in Ethiopia(10). Furthermore, though there is a plethora of evidence on predictors of MDR-TB outcome, there is a gap in evaluating the quality of the process, immediate, and intermediate outcome of the treatment service from a holistic perspective(32–34). The MDR-TB incidence is increasing in resource-scarce countries like Ethiopia(5).

St. Peter specialized hospital(SPSH) is the first hospital to start the MDR TB treatment in the country. It is a center of excellence for the treatment of drug-resistant TB including XDR TB(Extensive Drug resistance Tuberculosis) (35). From the hospital of enrolled 1400 patients, the treatment success rate is 73%. Whereas, the cure rate is only 54%. This is lower than the expected success (80%) and cures rate (60%). However, the reason is not assessed from a holistic perspective yet. Furthermore, delay to start the chemotherapy in SPSH is observed and also significantly associated with poor treatment outcomes (36). Nevertheless, the reason why the delay happened is not assessed yet.

The compliance to the guideline is another decisive issue that needed to be investigated. Failure to comply with the guideline is one of the reasons why we now facing such a brutal and deadly drug-resistant strain of TB in the first place(37). Furthermore, early diagnosis and successful treatment outcomes are vital national strategies to reduce the incidence and prevalence of MDR-TB cases.

Ensuring patient satisfaction is also one of the strategies recommended by the NTG(10). Therefore, there is a gap in assessing those perspectives of the treatment services in the country.

There are some researches done in the hospital to assess the determinant factors of MDR TB (5,14). However, to the best of our knowledge, there is a shortage of program-level evaluations done in the hospital. It is very crucial for the MDR-TB treatment service (38). Therefore, this study tried to identify MDR-TB treatment service quality with the dimensions of availability of resources, compliance to the NTG, interim clinical outcome as well as patients' satisfaction.

1.3. Significance of the Evaluation

This evaluation will deliver information on the MDR TB treatment service quality in SPSH. The evaluation produced a sound understanding of service provision, health care planning, and management to improve the treatment service for the hospital. This will help to fill the gap of evidence on assessing the quality of the process of treatment on MDR-TB. It also helps to share the best practices of SPSH. Assessing the MDR TB treatment service quality may help as a baseline for further large-scale quality assessment. This evaluation may assist to improve the treatment services for the Ministry of Health(MOH), Addis Ababa Health Bureau(AAHB) in addition to SPSH since the hospital is a national center of excellence.

Chapter Two: Program Description of National Programmatic Management of Drug-resistant Tuberculosis in Ethiopia

2.1 Stakeholders Engagement

Stakeholders are persons, groups, or institutions that have a remarkable interest in how well the program performance is going and those with decision-making ability over it. This includes funders, public officials, implementers, and also beneficiaries(39). For an evaluation to be successful, the involvement of stakeholders is priceless. And their absence may threaten the evaluation process, result, and its utility(40).

The key stakeholders identified during the evaluability assessment include SPSH, Federal Ministry of Health, Global health committee(GHC), AAHB(Addis Ababa Health Bureau), MDR-TB patients' association, and patients. The stakeholders are selected based on their role in the program and evaluation. They were involved in delivering the necessary information during the EA(Evaluability Assessment). They participate in setting the part of the program selected to be evaluated, selection and prioritization of indicators, and setting the judgment scale for the dimensions and the program.

Table 1: Stakeholder matrix of MDR-TB treatment program evaluation in St. Peter specialized hospital 2020.

Stakeholders	**Role in the program**	**Role in evaluation**	**Interest or perspective in evaluation**	**Means of communication**	Level of importance
Federal Ministry of Health	Technical and Financial support Adaption of WHO guidelines supportive supervision, Capacity building, Resource Provision.	Source of information Indicator Identification Set judgment matrix	Use the evaluation result as an input for treatment service quality enhancement, Decision making, resource allocation	Telephone, Email,	High
Addis Ababa health bureau	Planning, financing, technical support, and monitoring and evaluation of the service	Source of information Problem identification Set judgment matrix	Utilization of evaluation findings for identifying the gaps and strengthen the treatment services.	Telephone, Email, face to face	High
St. Peter specialized hospital	Provision of diagnostic and treatment and post-treatment services Availing essential drugs and supplies for the treatment service Recording & reporting properly Mentoring the TIC and TFC centers	Problem identification source of data Selection of Indicators Set judgment matrix	The primary user of the evaluation for improvement of DR-TB treatment services.	Telephone face to face, email	High
MDR TB Patients	Beneficiaries of the treatment service	source of data problem Identification	Improvement of the provision of treatment services	Face to face	High

Global Health Committee	Recruitment of clinical experts Provisions of MDR-TB drugs Economical support for the eligible patients	source of data Problem identification	Use the findings for improvement of the treatment services through technical support.	Telephone, Email,	Medium
MDR-TB patients Association	Psychological support for the patients on treatment	Source of data	Enhancement of MDR-TB treatment service provision.	Telephone and face to face	Low

2.3. Goal

To contribute to the reduction of mortality and Morbidity due to MDR-TB and MDR-TB related factors in Addis Ababa by the end of 2020.

2.4. General objectives

- Ensure 90% of all people in Addis Ababa with DR-TB diagnosed and treated by the end of 2020.
- Ensure 90% of the key populations in Addis Ababa are diagnosed and treated by the end of 2020.
- Ensure 90% of people diagnosed successful and complete treatment with services to ensure adherence and social support, for drug-resistant TB by the end of 2020(3).

2.4.1 Specific objectives

- To Screen 2095 MDR TB suspects for DR TB with Expert by the end of 2020 G.C in SPSH.
- To Diagnose 147 cases of MDR-TB patients by the end of 2020 G.C in SPSH.
- To Provide socio-economic support for all eligible and marginalized MDRTB patients by the end of 2020 G.C in SPSH.
- Achieve an 85% treatment success rate for MDR-TB patients by the end of 2020 G.C in SPSH(35).

2.5. Major strategies

The National MDR-TB Implementation framework included the following points as main strategies to battle drug-resistant TB:

1. Continuous political commitment

- Tackling the root causes leading to the occurrence of MDR-TB
- Long-term investment of staff and resources
- Coordination of efforts between communities, local governments, and international agencies
- A well-functioning DOT PLUS program

2. Appropriate case-finding strategy including quality-assured culture and drug susceptibility testing (DST)

- ✓ Rational triage of patients into DST and the DR-TB Control Program
- ✓ Relationship with supranational TB reference laboratory

3. Appropriate treatment strategies that use second-line drugs under proper case management conditions

- ✓ Rational treatment design
- ✓ DOT Plus
- ✓ Monitoring and management of adverse effects
- ✓ Properly trained human resources

4. Continuous provision of high-quality SLDs.

5. Recording and reporting system designed for drug resistance-TB control programs. (3)

Program resources and activities

Input: The input component of the program is comprised of;

- Human resource: (1 senior expert, 2 general practitioners, 2 health officers, 9 nurses 3 laboratory personnel at the hospital).
- Infrastructure (isolated MDR TB ward, cough clinic, pharmacy, and laboratory, follow up OPD) and logistics.
- Medical supplies and drugs: (sputum cups, DST(Drug Sensitivity Test) and Culture equipment, gene expert machines, AFB microscope, SLDs, reagents).
- Budget (annual allocation of the budget from the government, internal revenue, and funding from donors).
- Monitoring and Evaluation Tools: Guidelines, reporting, and recording HMIS formats: (SOPS, at TB clinic & laboratory, MDR database, and HMIS database).
- IEC/BCC materials.

Activities: Every patient who has a cough will be screened by cough triage and do SLD-LPA(Second line Drug Line Probe Assay) or Gene Xpert for drug resistance and start the treatment regimen based on the NTP criteria. Furthermore, activities done at the hospital includes HID(Health Information Dissemination), screening (symptomatic & lab dx.), contact screening, mentorship on catchment health centers, give capacity building training for health professionals, receive and manage referred MDR suspects, treatment including MDR-TB, Screening of BMI, conduct baseline and follow up laboratory diagnostics, SLD side effects monitoring and reporting

through the database, XDR-TB cases in short long and individualized drug regimen, Follow up of TIC(Treatment Initiation Centers) & TFC (Treatment follow up centers), additional laboratory tests are done for HIV comorbid patients, Providing socio-economic support(payment for food and transport), Referral linkages with TIC and TFC centers Rx follow up, defaulter tracing, recording, and reporting.

Outputs: The immediate output of the program including

- Health professionals trained; health centers mentored.
- MDR cases Diagnosed and start treatment promptly.
- Patients started the treatment SLD side effects monitored and reported.
- HID(Health Information Dissemination) sessions conducted.
- HID sessions conducted.
- Patients received socioeconomic support((payment for food and transport).
- Referral cases accepted and manage.
- Reports reported to FMOH timely.
- HIV comorbid patients where additional tests received.

Outcome: The program outcomes include

- Increased number of culture conversion,
- Reduced number of lost follow up,
- Improved quality of information system.
- Number of MDR TB cases completed and Cured,
- Number of MDR TB cases cured,
- Increased success rate, and cure rate.
- Improved community awareness about MDR-TB.

Impact: Reduced incidence and prevalence rate of MDR-TB in relation with poor quality.

Reduced mortality rate due to MDR-TB in relation with poor quality.

Improved Quality of Life in relation with poor quality.

2.7 Logic model

Logic model is a vivid representation of the association of the activities of the program with the envisioned outcomes(41). The logic model below illustrates the input, activities, output, outcome and impact of MDR-TB treatment service quality in SPSH service and their relationship.

Problem statement

The continuing spread of Multi-drug resistant tuberculosis (MDR-TB) is one of the most urgent and difficult challenges facing global TB control. (42). The SPSH treatment success rate is only 73%. Besides, cure rate is only 54%. This is lower than the expected success (80%) and cures rate (60%). However, the reason is not assessed from the holistic perspective yet. Furthermore, delay to start the chemotherapy in SPSH is observed and also associated with poor treatment outcome(Zemedu and Bayray, 2015). Nevertheless, the reason why the delay happened is not assessed yet.

Program goals

To contribute for the reduction of incidence and Prevalence of MDR-TB By providing quality MDR-TB treatment services .

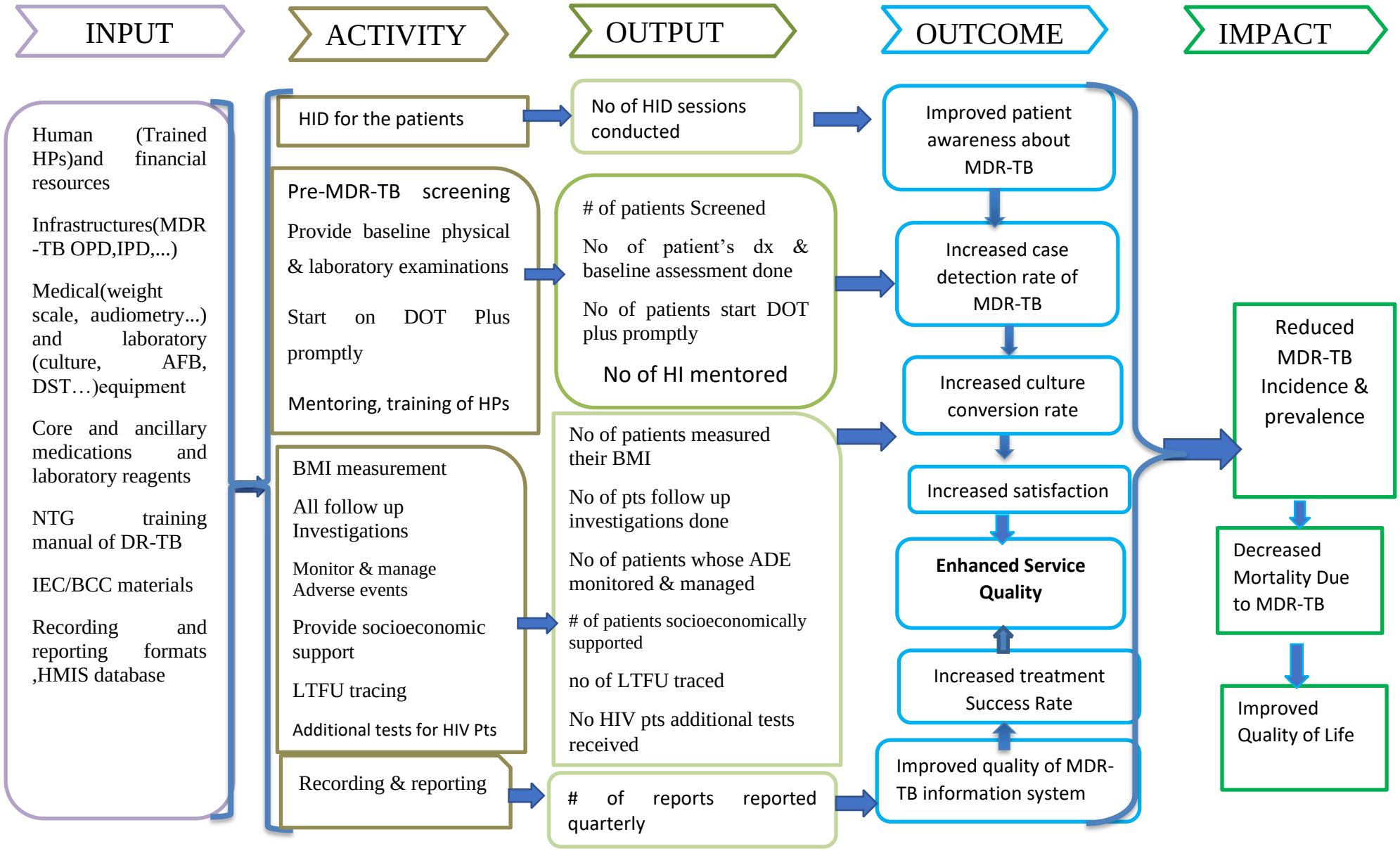

Figure 1, The Logic model of MDR-TB treatment service in SPSH Addis Ababa,2020

2.8. History and Stage of Development

The MDR-TB treatment program was started by the year 2009 with directives of MOH and collaboration with GHC and started in SPSH(St Peter's specialized Hospital). Then, later on, in Gonder Teaching hospital(43). SPSH was the first hospital in Ethiopia to start MDR-TB treatment by providing an isolated MDR-TB ward for the first time since 2009.

A decade has passed since the inception of the MDR-TB treatment program in the country. Consequently, the program is matured enough to be evaluated. There have been different improvements and additional treatment modalities and regimens were included in the program throughout the years of implementation. Therefore, this evaluation evaluated the performance of the treatment service process, immediate and intermediate outcome, successes and the mechanism, failures, and the reason behind the failure to improve the program and answer the stakeholder's questions. This evaluation assessed the quality of MDR-TB treatment service by using the following dimensions: the availability of resources, compliance as per the national guideline, (acceptance) satisfaction, and interim clinical outcome of the patients under chemotherapy.

Chapter Three: Literature Review-

MDR-TB is the result of compromised quality of care and patient-related international public health threat with prolonged expensive and less effective chemotherapy as compared with Drug sensitive TB (44). About the epidemiology of MDR-TB, Ethiopia ranked among 30 High burden countries with 166,000 individuals feeling ill, 27,000 TB related deaths by 2018 only. The meta-analysis done in 2017 indicate that there is no significant reduction in the prevalence of MDR-TB in Sub Saharan Africa(45).

3.1. Availability

Investing on the staffs' knowledge on MDR-TB, and scaling up of trained human resources, adequate and continuous supply of current SLDs, is one of the strategies to fight MDR-TB as recommended by NTG (3). However, there is a plethora of evidence that shows there is a gap in the availability of medical and laboratory equipment and materials. The study conducted in Vietnam indicates that there is a scarcity of SOPs (Standard Operating Procedure) and Guidelines, weak referral systems, temporary stock out of SLDs due to procurement postponement resulted in under screening, under-diagnosis and delayed enrollment to the treatment(44).

Another quality assessment on TB done in the Philippines show that 17% of treatment centers encounter a stock out in at least one of anti-TB drugs. Furthermore, only 34% of institutions have NTG (46). Moreover, the survey done in Nigeria indicates that 15% of the health facilities in the country claim stock out of a minimum of 1 of SLDs, and only 64% of the facilities have optimal drug storage space. Also, the NTG for drug-resistant TB is not available in 57% of the health institutions(47). The study done in southern Ethiopia show that 58% of patients reported poor adherence due to the absence of drugs(48).

The TB service provision assessment survey done in Ethiopia indicate that only 55%,35%,45% of referral, general and primary hospitals have a guideline for MDR-TB treatment services, respectively. Furthermore, only 20% of the hospitals in Addis Ababa has NTP guideline (49). However, the national guideline-recommended that every health institution giving Anti-TB treatment services should have updated guidelines (3).

The TB quality assessment study in 8 districts of Ethiopia discovered that 44% of the staff were untrained(37). Even though the NTG recommended giving training for the staff as a strategy to fight MDR-TB(3). Furthermore, there are a stock out of diagnostic equipment and too few gene Xpert machines in the country(10).

3.2 **Compliance**

According to Avedis Donabedian, "Quality is the product of two factors. The science and technology of health care and the application of that science and technology in actual practice"(2). When the actual practice is measured through compliance, one of the strategies to fight MDR-TB involves early detection and high-quality treatment. However, due to failure to comply with the guideline, there is poor adherence and unfavorable outcome for patients diagnosed with MDR-TB(3,10,49).

Drug-resistant TB is the result of poor compliance with the guideline and mismanagement of TB patients, which transmit the drug-resistant strain of TB to the community(47). Though the guideline recommends that promptly start treatment after the diagnosis, a study done in the Philippines indicates 21% of MDR-TB patients take more than 2 weeks to start treatment after the diagnosis(46). Additionally, the study done in China indicate that only 59% of health facilities can perform sputum culture and 44.4% provide DST test(50). Moreover, only 57%,46%,33% of the diagnostic services were given from the recommended for MDR-TB patients in tertiary, secondary, and primary health institutions in Nigeria, and also 15% of confirmed MDR-TB patients didn't start the treatment. Besides, only 44% of patients eligible for DST get the screening service(47). The cohort study was done in the Amhara region, indicates that patients with poor adherence to the treatment are associated with poor Outcomes and longer recovery time(51).

On the other hand, close monitoring of MDR-TB patients is an essential strategy as recommended by the NTG. By 2016, 10.5% of the patients were not evaluated(3,10). Furthermore, the study done in the southwest of Ethiopia indicates that 64.8% of presumptive TB cases did not receive sputum examination and 47% of diagnosed patients received the wrong dosage. Another quality survey done in 44 health facilities of Ethiopia indicate that 43% of the patients interrupt the therapy for more than 15 days(37). A systematic review and meta-analysis study done in Ethiopia discovered that drug complication is one of the contributing factors for the death of patients on the course of SLD treatment (52).

3.3. Satisfaction

Satisfaction is one of the treatment outcomes(2). To ensure the client's service utilization, health-seeking behavior, and increase adherence to the therapy, ensuring the patient's satisfaction is one strategy recommended by the NTG(10). Satisfaction is one of the measurement dimensions to assess the acceptance of MDR-TB treatment services from the vantage point of the patients.

A quality assessment done in the Philippines indicates that only 4% are dissatisfied with the TB treatment service. They reported that the reason for their dissatisfaction is health facility stigma and discrimination(46). A cross-sectional study done in India 80% of the patients was satisfied with DOTs. The reason for their satisfaction is a treatment-free from charge and the easy accessibility of the drugs in their nearby homes(53).

A mixed study done in Nigeria indicates that 13% and 7% of patients were indifferent and poor perception towards MDR-TB care. Marital status, employment, and monthly income are associated with the satisfaction of the patients(54). Furthermore, a study conducted in Southern Ethiopia indicates 90% of the patients were satisfied. The perceived increase in professional care, technical competence, and relational empathy associated with their satisfaction. It also shows that satisfaction is significantly associated with adherence to the treatment(48).

A mixed study done in Addis Ababa found that 33% of the patients were not satisfied by the DOT PLUS service rendered. From those dissatisfied patients, 14.5% and 5.6% of the patients relapsed and treatment failed (55). This clearly shows that satisfaction is associated with poor outcome.

3.4. Interim Clinical Outcome

Interim Clinical outcomes are a health status consequence of care (56). Delayed treatment outcome is a reason for unfavorable outcomes like pre-treatment LTFU, failure. This further increase transmission of MDR-TB strain. Monitoring the Outcome of MDR-TB is one of the strategies to fight MDR-TB (10). Globally by 2019, the treatment outcome of MDR-TB is very low (56%)(8). Systematic review and Meta-analysis done over 31 countries discovered the default rate is 14%(57). Additionally, a qualitative study in India uncovers that the patients are concerned about the effectiveness of the treatment(4).

In Africa, the outcome is a bit better than the globe which is 60%. Ethiopia has a better achievement regarding the outcome(72%)(6). Retrospective cohort research done in Northern Ethiopia indicates that the cured rate is 64%(51).

To summarize, the Avedis Donabedian framework of quality helps to assess quality from the three broad perspectives of quality(structure, Process and Outcome). This helps to frame the evaluation process in a broadest sense(2).

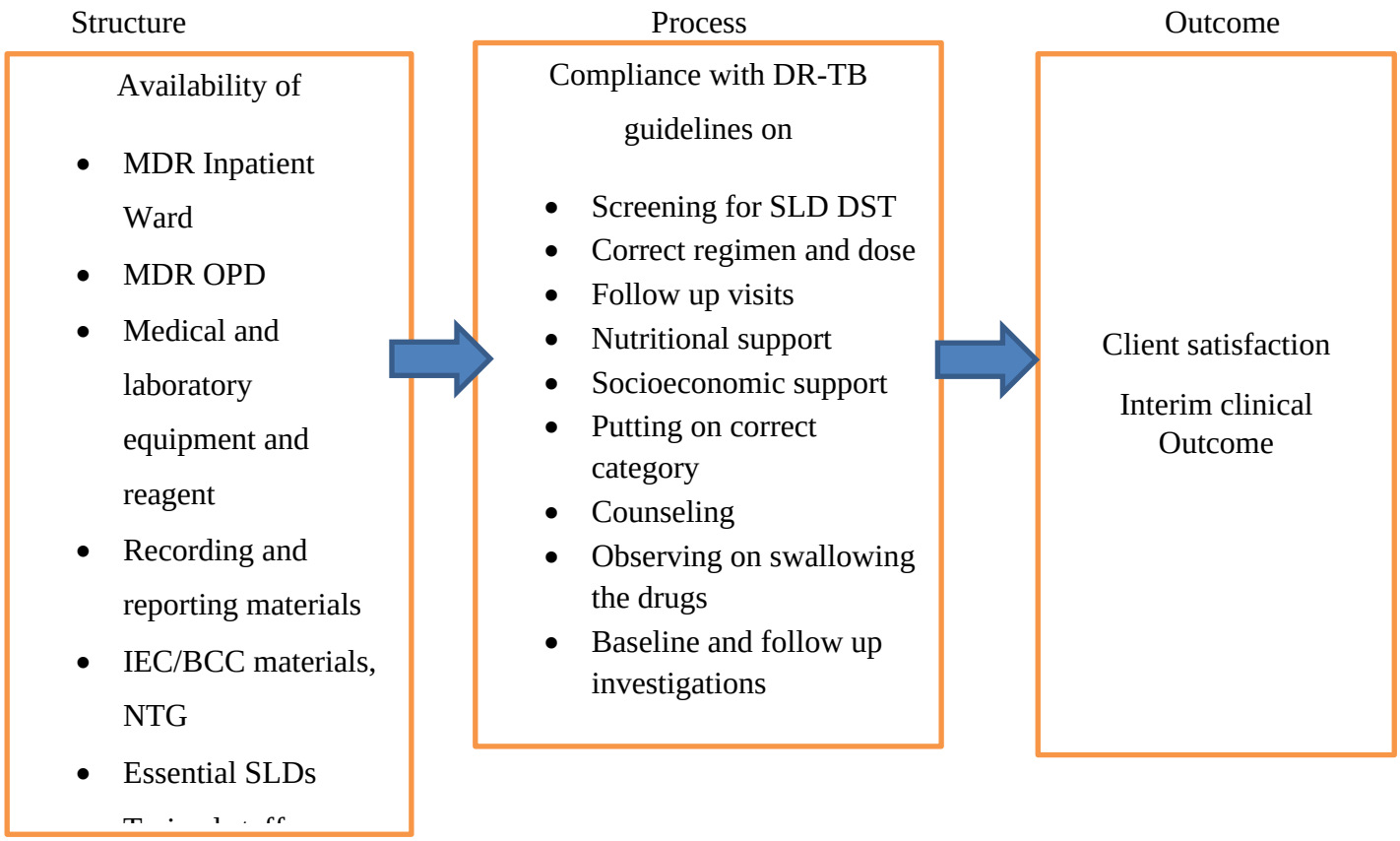

Figure 2 conceptual framework adapted from A quality assessment done in private clinics of Addis Ababa (58) *of evaluation of MDR-TB treatment services Quality in St. Peter specialized hospital, Addis Ababa, Ethiopia,2020*

Chapter Four: Evaluation Questions and Objectives

4.1. Evaluation Questions

1. Are the resources required to provide MDR TB treatment services available? If not, why? If yes how?

2. Is the treatment service implemented according to MDR TB national guidelines? If not, why? If yes how?

3. Are the clients utilizing MDR TB care in St Peter specialized hospital, Addis Ababa Satisfied with MDR TB treatment services provided to them? If not, why? If yes how?

4. Did the MDR-TB treatment service progress towards the favorable clinical outcome (Interim clinical Outcome)? If not, why? If yes how?

4.2 General Objective

To assess the MDR TB treatment service quality in St Peter specialized hospital, Addis Ababa Ethiopia, 2020.

4.2.1 Specific Objectives

1. To examine the availability of resources required to provide MDR TB services in St Peter specialized hospital, Addis Ababa, Ethiopia.

2. To describe the compliance of MDR TB service providers with the national MDR TB treatment guidelines in St Peter specialized hospital, Addis Ababa, Ethiopia.

3. To determine the level of client satisfaction among users of MDR TB services in St Peter specialized hospital, Addis Ababa, Ethiopia.

4. To determine the Interim clinical outcome of patients with MDR TB in St Peter specialized hospital, Addis Ababa, Ethiopia.

Chapter Five: Evaluation Methods

5.1. Study Area and period

The study was conducted in St. Peter specialized hospital in Addis Ababa. Addis Ababa is the center metropolitan of Ethiopia with an inhabitant of 3,384,569. The city is 527 square kilometers and the population density of 5.165 individuals per square kilometer available. The capital city holds one-fourth of Ethiopian live in urban areas(59).

SPSH was established in 1953. It has been serving the nation as the only tuberculosis hospital for more than four decades. But for the previous few years, the hospital grew from a single disease hospital into a multi-services health institution. (60). It is the first hospital to begin drug-resistant TB therapy in Ethiopia. By 2009, it was converted into an isolation ward. It is also the country's center of excellence for the treatment of drug-resistant TB (61).

The evaluability assessment was done from October 28 to November 3, 2019. The evaluation data were collected from March 1 up to April 15, 2020.

5.2. Evaluation Approach

A formative approach is an evaluative event done to provide information that will lead to program enhancement(39). The evaluation approach was formative evaluation. Because the main purpose of this evaluation was to identify and improve the program gaps. This evaluation assessed the quality of MDR TB treatment service in St. Peter specialized hospital to highlight the gaps.

5.3. Evaluation Design

A single explanatory case study design was selected. SPSH MDR-TB treatment service was the case. Because case study is a technique for a deeper understanding of a complex instance. It is also based on an inclusive comprehension of that instance and gained over extensive description and analysis of the treatment service taken as a whole and in its context(62).

5.4. The focus of evaluation and dimensions

The focus of Evaluation: - The focus of this evaluation was process. It also delivered a depth and comprehensive understanding of the input, process, the immediate and intermediate outcome of MDR-TB treatment services. Donabedian's framework for quality assessment was applied.

Because this framework enables the evaluator to assess quality from a structure, process, and outcome perspectives.

5.5. Dimensions of the Evaluation

Dimensions were measurable characteristics of the program showcase under evaluation. The evaluation dimensions have been chosen with stakeholders based on their evaluation questions. These evaluation dimensions helped to assess the MDR TB treatment services quality in St. Peter specialized hospital. The dimensions that were assessed the availability of necessary resources, Compliance of the staff with the national treatment guideline and the patient's interim clinical outcome, and their satisfaction with the service.

5.6.1 **Indicators**

The hospital MDR-TB unit and Addis Ababa health Bureau TB focal person have participated in the indicator selection process. It was based on the NTP guideline. However, some of them were drafted based on local situations and after skimming different articles done before. Since there is resource scarcity, a Delphi technique was applied to prioritize the indicators.

5.6.1.1 (Input) Availability Resources - availability of infrastructure(MDR-TB ward and OPD), trained human resources, essential drugs, laboratory equipment, NTGs, PPEs was assessed with 15 indicators. Those indicators are:-

1. Number of isolated MDR-TB inpatient beds as per NTG.
2. Number of MDR-TB OPD dedicated only for MDR-TB patients.
3. number of functional[1] culture testing laboratory[2] in the vicinity of the hospital
4. Number of functional Audiometry at the time of the assessment.
5. Number of functional ECG machine at the time of assessment.
6. Number of a functional Chemistry machine at the time of assessment.
7. percentage of the necessary SLDs present for the last three months.
8. Percentage of standardized PPE[3] present for all MDR-TB ward staff at the time of assessment.

[1] Functional means they were giving service at the time of data collection
[2] Presence of solid and liquid culture media and laboratory equipment for LPA and other DST tests

[3] PPE includes N-95 or PPF masks for the HPs and clients, gloves for health care professionals.

9. Number of a functional adult weight scale at the time of assessment.
10. Percentage of trained staff per the NTG from all staff at the time of assessment.
11. Number functional Gene Expert machine with all essential equipment[1] at the time of assessment.
12. Number of functional microscopes with all essential equipment for AFB at the time of assessment[2].
13. Number of updated NTG present in the MDR-TB unit at the time of assessment.
14. Number of Visual acuity test equipment present at the time of assessment.
15. Number of RUTF present as per the number of undernourished cases.

5.6.1.2- (Process) Compliance of the service provider to the national MDR-TB treatment protocol was assessed with 18 indicators.

1. The Proportion of patients whose baseline BMI is measured.
2. The Proportion of patients where all baseline[3] physical examinations were done.
3. The Proportion of patients where all follow up physical examinations were done at the end of 6 months.
4. The Proportion of patients where all routine blood tests were done at the end of 6 month
5. The Proportion of patients whose SLD-DST screening is done
6. The Proportion of HIV comorbid patients where additional lab tests[4] are done
7. The Proportion of MDR-TB patients who enrolled in a correct dose of treatment.
8. The Proportion of MDR-TB patients who were enrolled in the correct treatment regimen.
9. The proportion of MDR-TB patients' who received baseline culture test.
10. The Number of reports reported about adverse drug events of the patient under chemotherapy.
11. The Proportion of patients who received the post-treatment monitoring in the hospital.

[1] *Gene Xpert diagnostic system (the instrument and the computer), cartridges, Assay specific Gene Xpert cartridges, Printer, Surge protector(adaptor), triple package container.*

[2] *Functional Binocular light Microscopes, Slide, Frosted slide, Slide box, Sputum containers approved, Wire loops or sticks, Funnel, Filter paper, Staining rack, Sprit lamp/Bunsen burner, Lens tissue, Red pen Recording for positive result, Carbol fuchsine, Methyl blue 52 3% acid alcohol, Oil immersion, Forceps for holding slide and fixing, Alarm clock 56 5% phenol or 10% Sodium hypo chloride.*

[3] *Baseline means at the time of the diagnosis.*

[4] Additional tests are CD4 count and Viral load.

12. The proportion of bacteriologically confirmed patients for whom sputum culture follow up performed at the end of 6 months of therapy.
13. The number of complete reports reported timely to FMOH.
14. The Proportion of MDR-TB patients counseled during MDR-TB DOT Plus service.
15. The proportion of MDR-TB patients observed while swallowing the drugs.
16. The proportion of MDR-TB patients whose malnutrition was managed.
17. The proportion of patients who were asked if they develop a new symptom.
18. The proportion of MDR-TB patients who were economically supported.

5.6.1.3**(Immediate Outcome) Acceptability/Satisfaction**; - To ensure the client's service utilization, health-seeking behavior, and increase adherence to the therapy ensuring the patient's satisfaction is one strategy recommended by the NTG(10). In this study, the overall patient satisfaction towards MDR-TB treatment service was assessed with nine indicators.

1. Percentage satisfaction mean the scale of MDR-TB patients satisfied with the in-patient service of the SPSH.
2. Percentage satisfaction mean the scale of MDR-TB patients satisfied the progress of their treatment
3. Percentage satisfaction mean the scale of MDR-TB patients satisfied with the convenience of DR-TB unit working hours
4. Percentage satisfaction mean the scale of MDR-TB patients satisfied with the time spent in the waiting room
5. Percentage satisfaction mean the scale of MDR-TB patients satisfied with the competence/knowledge of the providers of SPSH.
6. Percentage satisfaction mean the scale of MDR-TB patients satisfied with the adequacy of counseling
7. Percentage satisfaction mean the scale of MDR-TB patients satisfied with food support
8. Percentage satisfaction mean the scale of MDR-TB patients satisfied with the transport payment support
9. Percentage satisfaction mean the scale of MDR-TB patients satisfied with the overall quality of service

5.6.1.4 **(Intermediate Outcome) Clinical outcome**; - Indicate the progress in the clinical status of the patient after initiation of the treatment(63). It also helps to know whether the outcome is in the right direction or not.it was assessed by using 2 indicators.

1. The sputum conversion rate of new bacteriologically confirmed cases at the completion of the intensive phase of the treatment
2. The sputum conversion rate of previously treated bacteriologically confirmed cases at the completion of the intensive phase of the treatment

5.7. Sample size and sampling technique

St. Peter specialized hospital is purposefully selected because it is a center of excellence for drug-resistant TB treatment.

MDR-TB registers review: All (132) MDR-TB patient cards that were on chemotherapy for at least six months during the data collection period were reviewed.

Sample size for observation:

The sample size for observation of patient-providers interaction was determined based on the standardized USAID observation guideline recommendation 3-5 observation sessions per health care providers(64). Five observations per health care provider was done for the assessment of compliance for IPD and OPD visits. Direct observation was conducted while health care providers deliver SLDs DOT Plus treatment service at both departments. Two health professionals from each department(From in-patient and outpatient department) were observed. A total of 20 observation sessions were carried out using the observation checklist. The time of observation was on working days and weekends for those who provide on the weekend.

Key informant interview: The KII was conducted totally for thirteen individuals. Those are the CEO of the hospital, MDR-TB unit head physician and head nurse, two physicians and one DR-TB expert, one pharmacist of the MDR-TB unit, one expert from FMOH, one expert from Addis Ababa health Bureau, one expert from GHC, one representative from MDR-TB patients association, and two patients currently from short and long regimen.

Face to face interviews; -All **(**105) MDR TB patients who are on MDR-TB treatment in OPD and inpatient treatment department of SPSH and fulfill inclusion criteria were interviewed. Because the total patients under chemotherapy during EA was only 132 patients.

5.8. Study unit and unit of analysis

Study Unit for quantitative study: St. Peter specialized hospital, all MDR-TB patients currently under DOT Plus treatment, provider-patient interactions, and all registered MDR-TB patients for the last 2 years who have at least six months of follow ups.

Study Unit for qualitative study: St Peter specialized hospital , selected MDR-TB experts from IPD,OPD, pharmacy, and senior MDR-TB expert of the hospital, clinical coordinator, head nurse, and head of the hospital. Furthermore, selected program coordinators from FMOH,AAHB,GHC, MDR-TB patients association, patients.

5.9. Unit of Analysis

The primary unit of analysis: MDR-TB patients, DOT Plus treatment service providers in St. Peter specialized hospital.

Secondary unit of analysis: St. Peter specialized hospital.

5.10. Inclusion and exclusion criteria

Inclusion criteria:

- For the card review, all registered MDR-TB patients for the last two years who have at least six months of follow up.
- Assigned key informants working at least for six months.

Exclusion criteria; - Critically ill TB patients were excluded.

5.11 Data Collection method and tool

5.11.1. Data collection tool

A structured questionnaire for patient interviews and a structured checklist for observation, document review, for resource inventory were used. Besides, an interview guide was used for key informant interviews.

5.11.2 Data collection Procedure

Resource Inventory checklist: This tool was to help to assess the availability of program resources for the delivery of MDR-TB DOT Plus treatment. Moreover, the checklist includes questions that assess medical equipment, human resources, guidelines, recording, and reporting tools. The tool was adopted from national guidelines and WHO guidelines (10,13).

Document review: This tool was used to assess the compliance of TB DOT PLUS providers to national guidelines. The tool is adopted from national guidelines (10).

Observation Checklist: This tool was helped to assess the compliance of MDR-TB DOT plus providers with the national guideline standard while providing the treatment and provider-patient interaction. A tool is adopted from different literature(3,10,35).

Key informant interview guide: The tool was to help to supplement other findings. It includes general questions about how TB DOT Plus treatment has been going on, questions related to the availability of resources, compliance of TB DOT Plus providers, and questions related to an opinion about barriers to a high-quality treatment service and possible solutions. Interview guide with probes was used to clarify and dig out participants' response.

5.11.3. Data collectors

Overall, 3 data collectors and one supervisor were engaged from the study area Addis Ababa, out of the hospital. The selected data collectors were degree holders and trained MDR-TB treatment services that had experience in data collection. The supervisor was a health professional degree holder with an experience in supervision before. Document review and exit interviews were conducted by data collectors. Ambulatory patients were interviewed after they finished their OPD visit. The patients in the MDR-TB ward were interviewed in a separate procedure room while KII(Key Informant Interview) , resource inventory, and Observation were conducted by the principal evaluator.

5.12 Data analysis

Quantitative data were checked for completeness, edited, coded, entered into Epi data version 3.1 for cleaning, editing, and coding. Then, exported to SPSS 25.0 software and analyzed. And the finding was presented using descriptive statistics. client satisfaction was assessed based on 17 Likert based items acceptability dimensions. And, using Principal component analysis the items are reduced to 9 which explains the majority of shared variance. The overall patient satisfaction means score was applied to calculate the overall patient satisfaction. Patient satisfaction data were scored by transforming into percentages of scale mean score(%SM). The formula stated below was used to provide individual percentage mean score for every indicator and to realize the overall level of satisfaction for the study population, the mean of this score was taken(65). The patient satisfaction level was ascertained by the judgment parameter.

$$(\%\text{SM}) = \frac{(\text{Actual score} - \text{potential minimum score})}{potential\ maximum\ score - potential\ minimum\ score} \times 100\%$$

The Factor score was computed for each scale. Each assumption of linear regression was verified. by using the histogram/p-p plot distribution of normality was verified. By using the scatter plot, Linearity was checked. homoscedasticity was confirmed by examining distributions residual versus fitted scatter plots. The result revealed all assumptions were fitted. Then by conducting principal component analysis, The Kaiser-Meyer-Olkin Measure of Sampling Adequacy is >0.5. Also, Bartlett's Sphericity test is <0.05. The items with the reliability coefficient (Cronbach alpha)>0.7 were taken. Items with Communality>0.5 were retained. Any item cross-loaded was removed. Factor loading>0.4was considered each item (Annex 6 The principal component analysis Results).

Qualitative data were analyzed by Atlas ti version 7.1. The thematic analysis technique was used. First, the recorded data were transcribed and translated. Then the translated data were coded into different codes. Each code was categorized into different categories and then categorized into themes.

5.14-Data quality management

Data collectors and a supervisor were received training on the content of the data to be collected, data collection tools, ethical issues to be addressed during gathering the data, and how to communicate with respondents for 2 days.

The quantitative data gathering tool was pretested before data collection in 22 patients of ALERT hospital (20% of 110 MDR-TB patients in SPSH). Additionally, the data supervisor has also received training on how to manage the data collection process and the way to monitor the quality of data. Completeness of questionnaires was checked every day after data collection and any problems encountered were discussed with a supervisor and data collectors and solved immediately and daily. Incomplete or invalid data were treated as a missed value and exclude from the analysis to get maximum quality data before, during, and after data entry.

To assure the qualitative data quality, the KII was recorded using an audio recorder. Member check for the interviews (after the transcription, by summarizing main points and confirm with the interviewee), The initial results were shown for the peers to receive input (Peer debrief). Moreover, triangulation through different key informant interviews was employed.

5.15. Judgment parameter and matrix of analysis

Judgment Criteria was agreed up with the interest of stakeholders. Weight was given for each dimension in terms of their relative importance in the program by stakeholders. Dimensions of MDR-TB DOT Plus service quality was judged based on these pre-set judgment parameters to determine the quality of the treatment services.

The weighting of dimensions and indicators: weight was given for each dimension in terms of their relative importance in the evaluation. It was decided as 30% for Availability, 30% for compliance,15% for clinical outcome, 25% for patient satisfaction by the stakeholders' agreement.

5.16 Ethical consideration

Ethical clearance was obtained from the Institutional Review Board (IRB) of Jimma University, Faculty of Public Health. A formal letter was written from St. Peter specialized hospital and permission was obtained from managers of the Hospital. Verbal Informed Consent was obtained from participants. Respondents were well-versed that participation is voluntary and that they have full autonomy to withdraw the participation at any time they feel so. The privacy and confidentiality of the clients that were included in the evaluation were respected. The name and other confidential personal information of the respondents were coded. Any information was kept confidential and only used for evaluation purposes.

5.17 Dissemination plan

The findings will be presented for scientific community of Jimma university. Then, it will be submitted to Jimma University Institute of health science, department of health policy and management. After the approval of the department, the final document (both soft and hard copies) will be disseminated to stakeholders for ensuring the use of findings. Efforts will be made to publish the findings on the reputable peer-reviewed journal.

Chapter Six: Results

Resource Inventory was done for human resources, laboratory equipment, and core drugs for the MDR-TB treatment. To answer the compliance to the NTG question, One hundred thirty-two patient cards were reviewed and an observation session of twenty was carried out. Furthermore, a total of 105 out of 110 patients were interviewed to assess their satisfaction level. The rest five patients were not interviewed because they were critically ill to respond. Key informant interview of thirteen individuals were done.

6.1 Availability of resources

6.1.1 Human Resources

St. Peter's specialized hospital is under the direct jurisdiction of FMOH. As a result, every resource is directly supplied by the ministry. Regarding the human resource, SPSH MDR-TB case team human resource described below;-

Table 2 The number of available MDR-TB case team staff professions compared with the NTG in SPSH Addis Ababa Ethiopia, 2020

s.no	Type of profession	Standard number of human resources	Available number of human resources
1	Internist	1	1
2	General practitioners	3	5
3	Health officers	2	3
4	B.Sc. Nurses	6	12
5	Data clerk	1	1
6	Social Worker	1	1
7	Pharmacist	1	1

Regarding training, only 52,4% of the staff are received training. The senior expert, five general practitioners, and three Health officers have received the updated training. However, only two of the twelve nurses were trained in MDR-TB training. Concerning low access to training, the expensive cost of training is the main cause described by many of the respondents. The other reason mentioned for insufficient training is the rapidly evolving treatment protocol for MDR-TB is raised. As the senior expert added:-

"…. Of course, there is a gap in training access. Training is vital but also a resource-intensive activity and combined with a promptly changing treatment protocol that makes training access less frequent …" A 41 years old MDR-TB expert.

6.1.2 Infrastructures

Concerning the infrastructure of the ward, there is a well-isolated in-patient ward with forty-four beds. Though there is a water pipe, "usually" there is no water supply for the inpatient ward.

"… there is a shortage of water supply in the MDR-TB ward because of the elevation of the ward when constructed…." A 40 years old MDR-TB expert.

There is an isolated waiting area dedicated to MDR TB patients. There is also a separate sputum collection site solely for MDR-TB patients. Besides, the MDR-TB adult OPD is also well ventilated and only gives service to MDR-TB patients. The hospital also has a separate cough clinic and sample collection place. However, the updated manual is only available in softcopy. The rapidly changing treatment protocol of MDR-TB is the one reason for that.

"…. The main reason for this is that the therapy of MDR TB is fast evolving and rapidly updating the treatment protocol. Frequent updates make it difficult to have a published guideline." A 41 years old MDR-TB expert.

6.1.3 Availability of Core Second Line Drugs

Among nine core SLDs, amikacin and linezolid were out of stock. The core SLD of MDR-TB is presented by the table below (Table 2).

Table 3 The core MDR-TB drug inventory of the SPSH Addis Ababa, Ethiopia 2020

The core SLDs based on the NTG recommendation.			Presence of Core SLDs in SPSH Presence of Core SLDs in SPSH			
			At the time of assessment	For the last 3 months	Days out of stock at the day of the visit	Days out of stock for the last 3 months
Presence of core SLDs	Group A	Bed aquiline (Bdq)	Yes	Yes	0 days	0 days
		Levofloxacin (Lfx)	Yes	Yes	0 days	0 days
		Moxifloxacin (Mx)	Yes	Yes	0 days	0 days
		Linezolid (Lzd)	No	No	1 day	2 days
	Group B	Clofazimine (Cfz)	Yes	Yes	0 days	0 days
		Cycloserine (Cs)	Yes	Yes	0 days	0 days
		Amikacin (Amk)	Yes	No	0 days	3 days
		Delamanid (Dlm)	Yes	Yes	0 days	0 days
		Protionamide (Pto) or Ethionamide (Eto)	Yes	Yes	0 days	0 days
	Pyridoxine		Yes	Yes	0 days	0 days
	RUTF		No	No	1 day	3 months

The reason why Linezolid and Amikacin are stock out is due to communication setback drug supply chain system within the hospital as described by the pharmacist as:-

"…. The stockout is because of the gap in the communication between the store and MDR-TB department not because of a shortage of drug supply…" A 29 years old pharmacist

For the RUTF(Ready To use therapeutic Feeding) supply problem, the program didn't have its own supply dedicated to MDR-TB patients. As explained below by the nurse in the hospital.

"….. The program didn't have its supply of plump -nut from FMOH…. We have been treating patients by borrowing from the *ART or pediatrics department of the hospital. And, now there is no Plumpy-nut for the last six months…" A 29 years old male nurse.*

6.1.3 Laboratory service availability

The availability of necessary laboratory equipment and reagents are crucial for the baseline and follow-up investigation services. There is an isolated sample collection site for MDR-TB patients only. However, there are no DST [1] Diagnostic tools including LPA Assay[2], Phenotypic DST tests. The inventory results of the laboratory service availability are described by the table below.

Table 4 The availability of necessary laboratory tests and equipment in SPSH, Addis Ababa, Ethiopia 2020

The necessary laboratory equipment based on the NTG standard	Presence of necessary laboratory equipment in SPSH	
	At the time of assessment	In the last three months
Availability of gene Expert MTB/RIF cartridge	Yes	No (for 7 days)
Presence of CBC Machine	Yes	Yes
Presence of Chemistry machine	Yes	Yes
Presence of HCG kit	Yes	Yes
Presence of Hepatitis testing kit	Yes	Yes
Presence of Glucosure kit	Yes	Yes
Presence of functional X-Ray machine	Yes	Yes
Presence of functional ECG machine	No	No (For 21 days)
Presence of functional Audiometry	Yes	Yes
Presence of a functional CD4 Machine	Yes	Yes
Presence of HIV/AIDS testing kit	Yes	Yes
Presence of a functional viral load machine	No	No (For 90 days)

The main resource gap is the absence of a culture laboratory in the vicinity of the hospital. It is under construction, but not functional yet. As the hospital expert explained it as follows *"…. The main resource issue is related to culture and DST service. Though it is under construction, the culture laboratory is not finished and functional yet. So, the service isn't available here…" A 41 years old expert.*

[1] *Isolated biosafety checked culture laboratory with capability of solid and liquid culture and LPA tests*

[2] *Presence of solid and liquid culture media and laboratory equipment for LPA and other DST tests*

The other resource gap observed is the frequent malfunctioning of the ECG machines and interruptions of supply of reagent.

Judgment Matrix of availability dimension

The MDR-TB treatment service quality concerning program resource availability was good 77.7% based on the judgment parameter.

Table 5 Judgment parameter for the availability of necessary resource and equipment for MDR-TB treatment service in SPSH Addis Ababa Ethiopia, 2020

Availability Indicators	Expected (a)	Observed (b)	Weight given	Score (b/a) *c	Observed %	Level of quality
Number of isolated MDR-TB inpatient beds as per NTG.	10	44	9	9	100	≥85%=Very Good, **75% - 84% = Good,** 60% - 74% = Fair, <60% = critical
Number of MDR-TB OPD dedicated only for MDR-TB patients.	1	1	7	7	100	
Number of functional culture testing laboratory[1] in the vicinity of the hospital	1	0	7	0	0	
Number of functional Audiometry at the time of the assessment.	2	5	5	5	100	
Number of functional ECG machine at the time of assessment.	1	0	4	0	0	
Number of functional Chemistry machine at the time of assessment.	1	1	6	6	100	
percentage of the necessary SLDs present for the last three months.	9	7	9	7	77.7	
Percentage of standardized PPE[2] present for all MDR-TB ward staff at the time of assessment.	21	21	7	7	100	
Number of a functional adult weight scale at the time of assessment.	2	2	7	7	100	
Percentage of trained staff per the NTG at the time of assessment.	21	11	9	4.7	52.4	
Number functional Gene Expert machine at the time of assessment.	1	1	8	8	100	
Number of functional microscopes with all essential equipment for AFB at the time of assessment[3].	1	2	6	6	100	
Number of updated NTG present in the MDR-TB unit at the time of assessment.	1	2	6	6	100	
Number of Visual acuity test equipment present at the time of assessment.	1	1	5	5	100	
Number of RUTF present as per the number of malnourished cases.	65	0	5	0	0	
Overall score			100	77.7	**77.7%**	

[1] Presence of solid and liquid culture media and laboratory equipment for LPA and other DST tests

[2] PPE includes N-95 or PPF masks for the HPs and clients, gloves for health care professionals.

[3] *Functional Binocular light Microscopes, Slide, Frosted slide, Slide box, Sputum containers approved, Wire loops or sticks, Funnel, Filter paper, Staining rack, Sprit lamp/Bunsen burner, Lens tissue, Red pen Recording for positive result, Carbol fuchsine, Methyl blue 52 3% acid alcohol, Oil immersion, Forceps for holding slide and fixing, Alarm clock 56 5% phenol or 10% Sodium hypo chloride*.

6.2 Compliance of health care professionals to the guideline

6.2.1 Communication with patients

From 16 provider-patient interaction observed, 14 (87.5%) were greeted politely. Whereas, 15 (93.7%) of the health professionals used clear language of communication. Furthermore, 14 (87.5%) of the patients were asked if they have any questions about the treatment. And 14 (87.5%) of the respondent's questions were replied. However, less than half of the patients 7 (43.8%) were asked if they missed any dose of the chemotherapy. However, all of the patients counseled on the dangerous consequences of defaulting the treatment. On the other hand, only a quarter of the patients 4(25%) were counseled about the importance of adherence to the treatment. Furthermore, greater than half of the patients 11(68.8%) were asked if there is a new symptom. Concerning the very low counseling issues, one of the health care professionals described as follow;

"…. Some of our staff only give counseling when the patient first diagnosed and started the treatment. …. Therefore, we usually didn't give counsel on the importance of adherence in follow up visits……" a 29 years old male respondent.

Despite this, among 8 observations in the in-patient department, all of the patients 8(100%) were observed while swallowing the MDR-TB tabs.

"…The nurses always observe while the patients swallow the PO drugs. And give the injectable as prescribed…." A 25 years old female nurse

Among the 132 cards reviewed, more than half of the patients were male (52.3%) as described by the table below.

Table 6 Description of the patient's demography and MDR-TB clinical conditions in St peter specialized hospital, Addis Ababa, Ethiopia 2020.

Variables		**Frequency(n)**	**Percentage (%)**
Sex	Male	69	52.3%
	Female	63	47.7%
Age	0-14	15	11.4%
	15-49	112	84.8%
	>49	5	3.8%
Type of TB	PTB	108	81.8%

	EPTB	24	18.2%
Category of patients	New	58	56.1%
	Previously treated	74	43.9%
Treatment regimen	Short	45	34.1%
	Long	87	65.9%

6.2.2 Physical examinations

A baseline (the investigations and physical examinations at the time of diagnosis) and six months follow up of 132 charts reviewed. Among those reviewed patients at baseline, 128(97.7%) of the patients have a vital sign as illustrated by the graph below (figure 3).

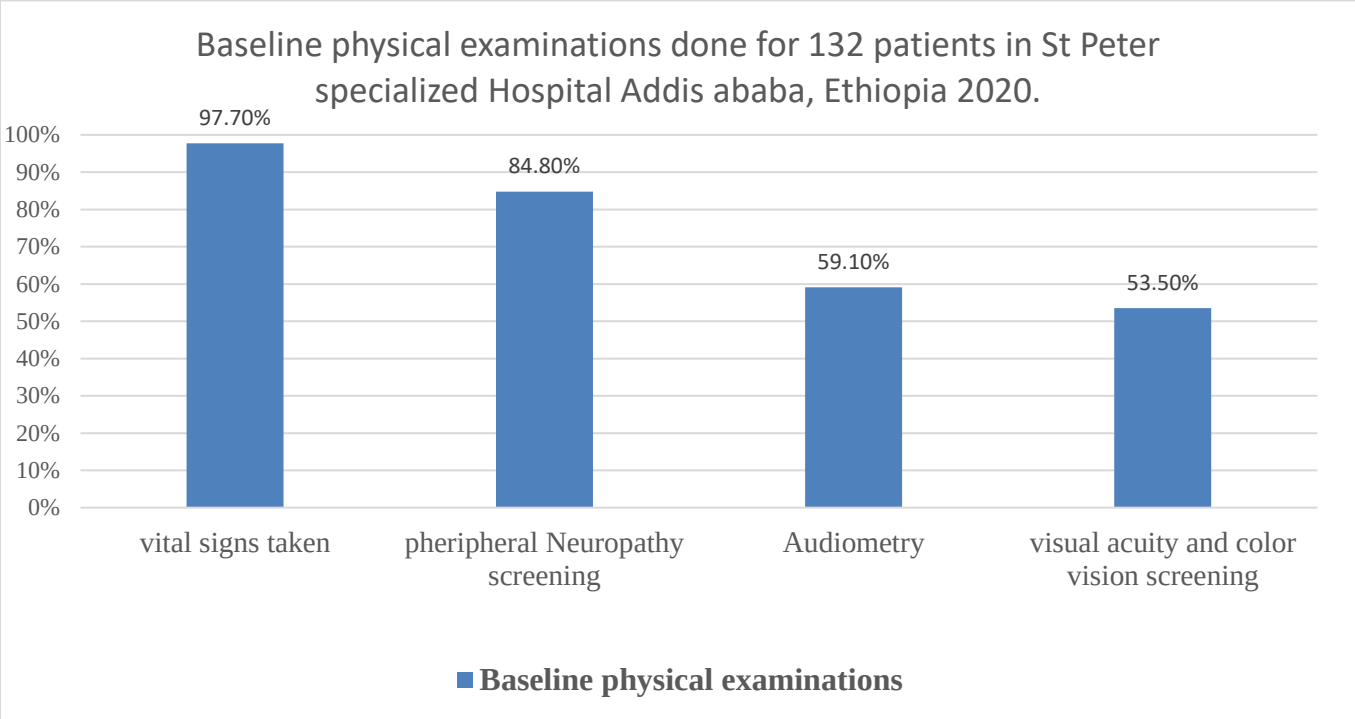

Figure 3 Baseline physical examinations done for 132 patients in St Peter specialized Hospital Addis Ababa, Ethiopia 2020.

The initial six months of the patient follow up test data were collected to assess the compliance of the health care professionals during follow up visits. The audiometry, color vision and visual acuity screening tests patterns for the first six months are very low. Whereas, around half of the patients screened for peripheral neuropathy. The physical examinations of the above-mentioned patients six months follow up are described by the graph below(figure 3).

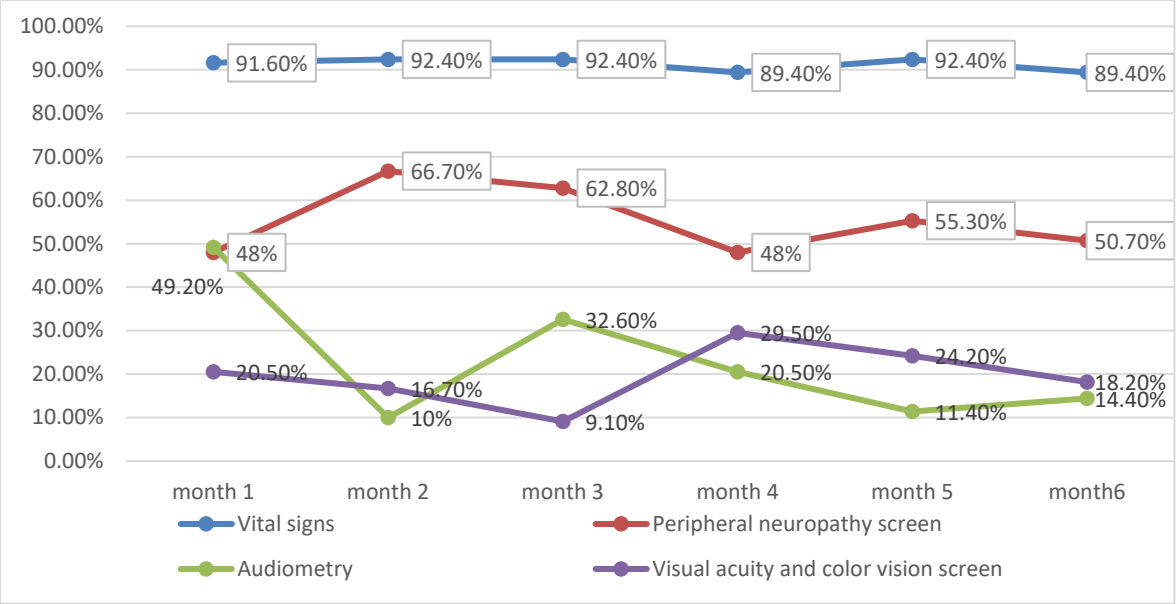

Figure 4 Follow up physical examinations done for 132 patients in SPSH, Addis Ababa, Ethiopia 2020.

There have been different reasons behind why the physical examinations except the vital sign tests are low. The first reason raised by most of the respondents is that the hospital's rotation policy of nurses and general practitioners every six months. The second cause is the interruptions in the supply of paper for color vison, and visual acuity tests. The third reason raised by the respondents is the inadequacy of the motivation of the staff.

"…The visual acuity tests are done by the nurses monthly for follow up. So, the schedule for the tests and a responsible nurse will be posted, but not implemented usually. Then, we will coach the nurses, and in the sixth month when they adapt the schedule and working based on the schedule, they will be transferred to other wards. Then, until the new staff fully understand their task the next two-three months the physical examinations and follow up tests will not be done correctly…." A 38 years old male clinician

6.2.3 Laboratory investigations

Baseline and follow up laboratory tests are an integral part of the MDR-TB treatment protocol. The baseline laboratory investigations were done for the patients including bacteriological tests like Culture, AFB, and SLD tests. One of the cornerstones of the treatment protocol is SL-DST which was done only for a quarter of the patients 34 (31.4%). There are two main explanations for the low SL-DST coverage according to the expert's response. The first one is related to the absence

of a culture laboratory in the hospital. The second is due to weak referral linkage with the outsourced laboratory, which is EPHI(Ethiopian Public Health Institute) laboratory.

The AFB test is also appeared to be done only half at baseline which is 55(50.1%). Then gets even lower at follow up tests. On average, less than half of the patients get AFB test on subsequent follow-ups. The baseline and follow up laboratory and radiologic tests are illustrated as following (Table 6): -

Table 7 Baseline and follow up laboratory and radiologic tests of SPSH MDR-TB patients Addis Ababa, Ethiopia,2020

Radiologic and laboratory tests	Baseline n (%)	Month 1 n (%)	Month 2 n (%)	Month 3 n (%)	Month 4 n (%)	Month 5 n (%)	Month 6 n (%)
SL-DST	34(31.4%)						
AFB	55(50.1%)	51(47.2%)	44(40.7%)	43(39.8%)	43(39.8%)	39(36.1%)	43(39.8%)
Culture Test	96(88.8%)	89(82.4%)	73(67.5%)	80(74.1%)	79(71.3%)	77(71.3%)	73(67.5%)
ECG	64(48.4%)	54(41%)	51(38.6%)	46(35%)	40(30.3%)	44(33.3%)	38(28.8%)
CBC	64(48.4%)	13(9.8%)	50(38%)	42(32%)	28(21.2%)	23(17.4%)	26(19.7%)
BUN	79(60%)	30(22.7%)	23(17.4%)	51(38.6%)	44(33.3%)	37(28.2%)	28(21.2%)
Serum Electrolyte	71(53.8%)	35(26.5%)	39(29.5%)	24(18.2%)	49(37.1%)	44(33.3%)	37(28%)
LFT	62(46.9%)	43(32.6%)	42(31.8%)	39(29.5%)	20(15.2%)	52(39.4%)	43(32.6%)
TFT	61(46.2%)			25(19%)			25(19%)
HBA\HCA	68(51.5%)						
FBS	63(47.7%)						

The culture test is done for 96(88.8%) of the patients at baseline. Nonetheless, throughout the follow up of the patients, 6% to 21.3% decrement is observed.

6.2.3.1 Chemistry tests

Baseline blood and radiological tests include ECG (Electrocardiogram), (CBC) complete blood count, BUN (Urea, creatinine), serum electrolytes, liver function test (LFT), TSH (Thyroid Stimulating Hormone) HBA & HCA (hepatitis B antigen and hepatitis C Antibody Test) and FBS(Fasting Blood Sugar).

The ECG tested patients at baseline is nearly half 64(48.4%). Moreover, there is a decrement of a minimum of 7.4% and a maximum of 19.6% in the follow-up tests. For CBC tests, at baseline, 64(48.7%) of patients were tested but the number of patients tested in subsequent follow-ups is decreased in the range from 3.7% up to 31.9%. The first justification is the repeated malfunction of ECG machine. The other reason for low baseline and follow up blood test is the interruptions of reagent supply for the chemistry test. As the clinician described as follow as

"……The reagent supply interruptions happen sometimes in the hospital…. maybe the clinician didn't order the test or maybe the results are not attached to the chart…" A 46 years old male General practitioner

6.2.4 **Regarding Integrated Supportive supervision**

The SPSH is under direct administration of FMOH. Therefore, it is expected to have a quarterly Program specific and integrated supportive supervision with timely written feedback. In this budget year, there has not been any supervision from the expected three times. One of the program coordinators in FMOH admitted that:

"….We didn't perform integrated supportive supervision in SPSH this year…" A 38 years old male MDR TB coordinator in FMOH.

6.2.5 Regarding Drug adherence

From 132 patients reviewed, 130 patients were put on the correct regimen which is 98.5%. Besides, 128 of the patients were put on a correct dose which is 97%. Conversely, the rest of the 4 patients' weight was didn't record on the chart. As 20 years old patients confirm as following

"…I have been taking the MDR-TB drugs for the past 9 months. But, I have never once missed a single dose …." A 20 years old male patient

Only 8(23%) patients were gotten the post-treatment follow up after they completed their treatment. The rest 27 (77%) patients didn't get the post-treatment follow up. The reason for this low post-treatment follows ups are described as follow as; -

"…The pot treatment follows up is low because our hospital is a national treatment center. Hence, patients came from every corner of the country. That makes it difficult for the patients……our staff may not counsel the importance of post-treatment counseling …" A 29 years old clinician

Judgment Matrix of compliance of health professionals to the guideline

Based on the judgment parameter, the level of compliance of MDR-Providers with national treatment guideline was fair (68%) (Table 8).

Table 8 Judgment matrix for compliance of MDR-TB DOT PLUS services providers to NTG in SPSH, Addis Ababa, 2020.

Compliance Indicators	Expected (a)	Observed (b)	Wt. given(c)	Score (a/b) *c	Level of quality
The Proportion of patients whose baseline[1] BMI is measured	132	73	6	3.3	≥85%=Very Good, 75% - 84% = Good, **60% - 74% = Fair**, <60% = critical
The Proportion of patients where all baseline physical examinations were done.	132	61	7	3.2	
The Proportion of patients where all follow up physical examinations were done the end of 6 month.	132	24	5	1	
The Proportion of patients where all routine [1]blood tests were done at the end of 6 month	132	25	6	1.2	
The Proportion of patients whose SLD-DST screening is done	108	34	7	2.3	
Proportion of bacteriologically confirmed patients for whom baseline sputum culture performed .	108	96	6	5.3	
The proportion of MDR-TB patients' monthly culture were performed at the end of 6 months.	108	73	6	4.8	
The Proportion of HIV comorbid patients where additional lab tests are done	30	30	4	4	
The Proportion of MDR-TB patients who enrolled in a correct dose of treatment.	132	128	9	8.7	
The Proportion of MDR-TB patients who were enrolled in the correct treatment regimen.	132	130	9	8.9	
The Proportion of MDR-TB patients counseled on adherence during TB DOT service	16	4	4	1	
The Number of complete reports reported about adverse drug events of the patient under chemotherapy.	3	3	7	7	
The Proportion of patients who received the post treatment monitoring service in the hospital.	35	8	3	1.6	
The proportion of MDR-TB patients observed while swallowing the drugs.	42	42	7	7	
The proportion of patients who were asked if they develop a new symptom	16	11	3	2.1	
The proportion of MDR-TB patients whose malnutrition was managed	35	0	3	0	
The number of reports reported timely to FMOH	3	3	4	4	
The proportion of MDR-TB patients who were economically supported.	70	46	4	2.6	
Overall score			**100**	**68%**	

[1] Baseline means the physical and laboratory examinations done for the patient at the time of diagnosis

6.3 Interim Clinical Outcome

Among those patients reviewed charts, 108 patients are pulmonary TB patients. Of those PTB patients, 56% (58) patients were previously treated for TB. But, the rest 50 (44%) patients are newly diagnosed PTB patients. The overall culture conversion rate in this study is 88%.

Among 132 patients reviewed, the following table 9 summarizes the status of the patients. From those 71 is still on the treatment. Therefore, the rest is posted below; -

Table 9 The clinical outcome of 61 MDR-TB patients who finished the treatment reviewed in SPSH, Addis Ababa, Ethiopia 2020

Treatment status of the patient	**frequency**	**Percentage**
Cured	1	1.63
Tx Completed	34	55.7
Dead	1	1.63
Move to XDR TB register	8	13.11
Lost follow up	8	13.11
Not evaluated	9	14.75
Favorable outcome or Treatment Success Rate	**35**	**57.4**
Unfavorable	**26**	**42.6**
Total	61	100

The respondents explained the higher unfavorable outcome and culture reversion back to the positive. Nearly every one of the respondents raised as the first cause is the inadequacy of social support to the patients. It affects both adherence and favorable outcome to the treatment. The 53 years old general practitioner said *"…most of our patients are very poor and destitute and need economic support…. So nowadays after the patient is culture-negative and goes back to the community, ……. They default the medication and came back with the same disease when you ask them why they defaulted they said because of economic problems…." 53 years old male general practitioners*

[1] Routine means the physical and laboratory examinations done for the patient at follow up visit

The second cause is that the weak referral linkage between SPSH and other TIC and TFC centers across the country. The third reason is inadequate nutritional management due to the inconsistent supply of Plump-nut and the high protein diet provided for the MDR-TB ward.

Judgment Matrix of Interim clinical outcome

Based on the judgment parameter, the level of interim clinical outcome of MDR-TB providers is Very good quality (88%).

Table 10 judgment matrix of interim clinical outcome of MDR-TB patients in SPSH, Addis Ababa, Ethiopia 2020

Variables	Expected (a)	observed(b)	Weight given(c)	Score (b/a) *c	Level of quality
Proportion of bacteriologically confirmed new DR-TB cases who were culture-positive but reverse back to culture negative during phase of treatment	50	44	50	44	**≥85%=Very Good**, 75% - 84% = Good, 60% - 74% = Fair, <60% = critical
The proportion of bacteriologically confirmed previously treated DR-TB cases who were culture-positive but reverse back to culture-negative during the phase of treatment	58	51	50	44	
Total			100	**88%**	

6.4 Patient Satisfaction with the MDR-TB treatment Services

During the data collection period, there are 110 MDR-TB patients in SPSH. Among those 105 patients were included in this study. This makes the participants response rate of 95.5%. Because the rest five patients were too sick to answer. Then, the overall patient satisfaction means score was applied to calculate the overall patient satisfaction.

Majority of the respondents are male. Most of the patients are the productive segment of the population as mentioned below in the table 11.

Table 11 shows the Socio-demographic characteristics of MDR-TB patients in SPSH Addis Ababa, Ethiopia 2020

Variables		**Frequency**	**Percentage**
Sex	Male	56	53.3%
	Female	49	46.7%
Marital Status	Single	58	55.2%
	Married	25	23.8%
	Divorced	16	15.2%
	Widowed	4	3.8%
	Separated	2	1.9%
Place of residence	In Addis Ababa	70	66.7%
	Out of Addis Ababa	35	33.3%
Age	0-14	2	1.9%
	15-49	95	90.5%
	>49	8	7.6%
Level of Education	No formal Education	32	30.3%
	Primary school	25	23.8%
	Secondary school	26	24.7%
	Diploma and Above	22	21%
Occupational level	Jobless	62	59%
	Private work	14	13.3%
	Temporary work	10	9.5%
	Governmental work	9	8.6%
	Student	9	8.6%
	Retired	1	1%
Religion	Orthodox	81	77.1%
	Protestant	9	8.6%
	Muslim	11	10.5%
	Catholic	2	1.9%

The majority of the patients (69.5%) are new MDR-TB patients as presented by the table below (Table 11).

Table 12 shows the general characteristics of MDR-TB patients in SPSH Addis Ababa, Ethiopia 2020

Variables		**frequency**	**Percentage**
Type of MDR-TB	bacteriologically Confirmed MDR[1]-PTB	67	63.8%
	clinically diagnosed MDR -PTB[2]	36	34.3%
	Extra-pulmonary MDR TB	2	1.9%
Treatment regimen	Short	21	20%
	Long	80	76.2%
	Individualized	4	3.8%
Category of patients	New	73	69.5%
	Relapse	24	22.9%
	Treatment after failure	7	6.7%
	Return after lost to follow up	1	1%
follow up department	OPD	63	60%
	IPD	42	40%

The majority (89%) of the patients pleased by the convenience of working hours and the inpatients' services of the hospital(84.4%). In addition, they also satisfied with the progress of their treatment(82.8%) and the perceived knowledge of the health professionals(80.8%). In spite of this, the food(67.6%) and transport (48.5%) support delivered by the hospital is not satisfying for the majority of the interviewees. This result is supported by the KII.

"…. Sometimes the patients hold 20 tabs of MDR-TB medications and ask you a question saying how can I tolerate all this medication with "bread"? …." A 53 years old male physician

[1] Pulmonary Tb patients diagnosed by AFB or gene expert
[2] Pulmonary TB patient started-TB treatment with the decision of the clinician

Table 13 the Judgment Matrix for Satisfaction of MDR-TB patients' acceptability of treatment service in SPSH, A.A Ethiopia

Indicators of patient satisfaction on MDR-TB treatment service quality	Wight given (a)	Observed (b)	Score (a*b) /100	Level of quality
Percentage satisfaction mean scale of MDR-TB patients satisfied with the in-patient service of the hospital.	10.4	84.4	8.8	≥85%=Very Good, 75% - 84% = Good, 60% - 74% = Fair, <60% = critical
Percentage satisfaction mean scale of MDR-TB patients satisfied the progress of their treatment	11.1	82.8	9.2	
Percentage satisfaction mean scale of MDR-TB patients satisfied with the convenience of DR-TB unit working hours	12.2	89	10.9	
Percentage satisfaction mean scale of MDR-TB patients satisfied with the time spent in the waiting room	11.2	79	8.8	
Percentage satisfaction mean scale of MDR-TB patients satisfied with the competence/knowledge of the providers	11.8	80.8	9.5	
Percentage satisfaction mean scale of MDR-TB patients satisfied with the adequacy of counseling	11.8	70.7	8.3	
Percentage satisfaction mean scale of MDR-TB patients satisfied with food support	10.9	67.6	7.3	
Percentage satisfaction mean scale of MDR-TB patients satisfied with the transport payment support	12	48.5	5.8	
Percentage satisfaction mean scale of MDR-TB patients satisfied with overall quality of service	8.6	80.6	7	
Overall Result	**100**		**75.6**	

Based on the judgment matrix analysis the level of overall patient satisfaction mean score with the MDR TB treatment service quality was good (75.6%) (Table 12).

Summary of judgment matrix

The overall status of quality of MDR-TB treatment services in SPSH has good quality based on the weight given for each dimension (table13).

Table 14 Overall judgment matrixes and analysis of dimension of MDR-TB treatment services in SPSH, Addis Ababa, Ethiopia 2020.

Dimension	**Value given (a)**	**% achieved (b)**	**Value achieved(a*b)/100**	**Overall judgement criteria**
Availability	30	77.7	23.3	**75-84% Good quality,**
Compliance	30	68	20.4	
Satisfaction	25	75.6	19	
Clinical Outcome	15	88	13.2	
Total	**100**		**75.9%**	

Chapter Seven: Discussion

Based on the judgment parameter, the evaluation finding tests the overall MDR-TB treatment service quality of SPSH was good (75.9%). The availability of resources as compared with the NTG required was also good (77.7%). Besides, the compliance of the health care professional towards the NTG was fair (68%). The overall patient satisfaction mean score of MDR-TB patients was good (75.6%). Moreover, the Interim clinical outcome scored very good (88%).

7.1 Availability of Resources

Though the number of healthcare professionals was achieved as per the guideline, only 52.4% of the staff have got the MDR-TB training. But, the NTG recommends all staff in MDR-TB unit should be trained. The shortage of training adversely affects the compliance of the staff to the guideline in this study. Also, contradicts with WHO End TB strategy which dictates that all health care providers should get training. Because the trained staff is an integral part of the fight against MDR-TB (3,69). This low percentage of the trained staff is probably due to the rotation policy of the hospital and high staff turnover. This would adversely affect the staff's compliance with the NTG.

The MDR-TB Ward in SPSH has 44 beds dedicated solely for MDR-TB patients. This is more than the guideline recommends which is 11 beds dedicated for MDR-TB patients(3). There is secluded MDR-TB OPD with an isolated waiting area and sample collection site. However, there is a problem with access to a clean water supply. Inconsistent water supply may hinder the effective Infection prevention practice of the hospital and personal hygiene of the patients.

Concerning the core SLDs, among nine core drugs, two (22.2%) of them were out of stock temporarily. Amikacin was out of stock on the day of the visit. This may be due to the new recommendation of WHO to hold the injectable from all treatment regimens (13). However, the linezolid is out of stock for 2 days in the last 3 months. This may badly influence the treatment outcome.

Though the guideline considers the nutritional management of the integral component of MDR-TB management, the nutritional management supplies like Plumpy nut and plumpy sap were not

available for the last six months(10). This might be because of resource scarcity to avail the RUTF. It also could severely impede the favorable treatment outcome.

Concerning laboratory service availability, the guideline clearly states there should be a culture and DST laboratory in the hospital(10). However, SPSH didn't have the culture and DST laboratory. This might seriously threaten the laboratory service and affect the treatment to follow up care. In addition, it also hinders the effort to identify and manage XDR and MDR TB cases effectively.

7.2 Compliance of the healthcare professionals to the national treatment guideline

Standards are the tools for transforming the notions of quality to the assessable and practical measurements(2). When the actual practice is measured through compliance, one of the strategies to fight MDR-TB involves early detection and high-quality treatment. However, due to failure to abide by the guideline, there is poor adherence and unfavorable outcome for patients diagnosed with MDR-TB(3,10,66).

Having a clear communication channel between the healthcare provider and the patient is very imperative for good adherence to chemotherapy and have a favorable clinical outcome(3). In this study, 87.5% of health professionals have clear communication with patients. Whereas, an evaluation study conducted in Nigeria indicate that 92% which is in line with this study(47).

Counseling the patient on adherence to the therapy is a very vital component in treating MDR-TB. However, only 25% of the patients were counseled on adherence in -this study. Yet, the NTG recommends counseling every patient on MDR-TB chemotherapy(10). This could hamper the drug adherence and a favorable clinical outcome of the patients.

Tracking the adverse events of the MDR-TB drug is indispensable since the drug intolerance is one cause of poor adherence and treatment failure(3,19). Therefore, 68.8% of the patients were screened for adverse events of the MDR-TB drugs. The evaluation done in Nigeria showed that 76% of the patients were screened for adverse events of MDR-TB drugs(47). The result is comparable to this study.

The guideline recommends that all patients should have baseline physical examinations including vital signs, peripheral neuropathy screening, visual acuity ,audiometry, color vision testing, and BMI(3,10). However, only 59.1%, 55.5%, and 53.5% of the patients got audiometry, BMI and

visual acuity, and color vision testing respectively. The follow-up tests for those tests are even lower than the baseline. Especially the visual acuity and color vision testing and the audiometry gone as low as 18.2% and 14.4% respectively. This could obstruct the ability to detect the side effects of the drugs early and promptly and cause defaulters.

Regarding the laboratory investigations, only 31.4% of the pulmonary MDR-TB patients were tested for SLD-DST in SPSH. This is significantly lower than in tertiary hospitals in Nigeria which were 57%. This may be due to the absence of culture testing set up in the SPSH. Though the guideline recommends to do baseline AFB and Culture test for all patients, only done for 50.1% and 88.8% of the patients respectively(10). When the follow-up tests were reviewed, it is getting even lower with both of the bacteriological tests as low as 36% and 67.5% for AFB and culture tests respectively. This is significantly lower than the evaluation done in Bangladesh which shows 95% of the patients received all follow up laboratory test(67). The absence of a culture laboratory, the poor recording system, and the inconsistent supply of AFB and culture reagents could be the reason for the low coverage.

The blood chemistry tests are crucial to assess the side effect of the MDR-TB drugs and to decide on whether or not to have regimen change(3,10). The baseline and follow up tests of the CBC, BUN, serum electrolyte, LFT, TFT, HBA, and FBS were barely half of the expected patients are gotten the laboratory tests. This could impede the monitoring of drug side effects and cause a late diagnosis of serious drug complications. Uneven supply of reagents and poor documentation might be the reason.

The radiologic test of ECG is very important especially for the newly included drugs like bed-aquiline, Clofazimine, and linezolid. Because they are known to cause arrythmia. The screening of baseline and follow up ECG is very crucial(3,10). However, only 48.4% of the patients have baseline ECG. In addition, the follow up months show decrement ranges from 7.4% to 19.6%. The cause is maybe because of the repetitive malfunctions of the ECG machine. Besides, lack of service integration with other departments in the hospital is another explanation.

The nutritional management which is both therapeutic and supplementary food support is one of the components of the MDR-TB treatment protocol. BMI<18 is associated with a poor clinical outcome(17). The WHO and national guidelines recommend the management should include both therapeutic and supplementary nutritional supply(13,10). The evaluations done in the Philippines

indicate the social support is 9%(46). But, the social support in this evaluation study is 65%. The reason could be because SPSH is a national treatment center of the country.

7.3 Interim clinical Outcome of the patients

Monitoring the outcome of MDR-TB is one of the strategies to fight MDR-TB (10). Interim clinical outcome is a vital indicator of the Pulmonary MDR-TB treatment progress and an intermediate outcome of the service. It helps the provider to monitor the progress of the treatment. It also is vital whether the regimen change is important or not before the patient took the toxic SLDs for additional five to eighteen months. So, it is a crucial intermediate outcome for bacteriologically confirmed patients to know the culture result.

The overall culture conversion rate in this study is 88%. The study done in Bangladesh show that the culture conversion rate is 98%(67). The discrepancy is may be due to low coverage of follow up culture tests in SPSH.

7.4 Satisfaction of MDR-TB patients on MDR-TB treatment Services

Ensuring patient satisfaction is one of the strategies to increase treatment adherence and the health-seeking behavior of the patient. It is also an immediate outcome of the treatment services(2). The overall patient satisfaction mean score with the MDR TB treatment service quality was 75.6%.A cross-sectional paper done in Nigeria shows 78% of the patients was satisfied with DOT PLUS(54). This is in line with this study. In this study, the patients were satisfied with the convenience of DR-TB unit working hours, in-patient service of the hospital, and progress of their treatment. On the other hand, payment of transport support and food support were the issues that the patients are dissatisfied within this study. The cause might be due to the hospital only gives the support for selected few patients.

The interruptions of reagents, frequent malfunctions of medical equipment. and the rotations inadequate commitment of the staff, and insufficient social support might be the reasons for 27.4% of patient dissatisfaction.

Limitation of the study

- Throughout the observation of the interaction of patient with health care professionals, the Hawthorn effect is inevitable. However, the evaluator has tried to minimize the effect by dropping a total of 4 observations from each provider patient interaction from the analysis.

- Throughout the interview, the respondents may answer positively in the fear of being recognized. To mitigate this gap, the data collectors came from other hospitals, and the inpatients were interviewed in a private room.

Chapter Eight: Conclusion and Recommendations

8.1 Conclusion

Based on the judgment parameter, the availability of resources for providing quality of MDR-TB treatment quality services was found to be good. Yet, the scarcity of trained staff, stock out of SLDs, interruptions reagent and RUTF, frequent malfunctions of equipment, inconsistent physical examinations, and absence of functional culture set up though under construction were the gaps found in this study.

Based on the judgment parameter, the compliance of the health professional to the guideline was fair. Besides, all patients were seen when swallowing their medication in the ward. On the other hand, only one-third of patients were SL-DST were done. Furthermore, social support was hardly covering demand and counseling on adherence is low. Inadequate supportive supervision, low post treatment follow up and poor documentation also noticed. Based on the judgment parameter, the interim clinical outcome was very good. The overall culture conversion rate is 88%.

Furthermore, according to the matrix of judgment for the clients' satisfaction level was good. The indicators with a higher rate were convenience of DR-TB unit working hours, in-patient service of the hospital, and progress of their treatment. however, payment of transport support and food support are the issues that the patients need improvement.

8.2 Recommendations

Based on the finding of the evaluation, the following recommendations are forwarded.

For the Ministry of Health :

- The culture laboratory which is under construction should be finalized and be functional.
- The resources for nutritional therapeutic and supplementary food should be availed for the hospital by channeling the resources from governmental and non-governmental organizations.

- The program-specific integrated supportive supervision with timely written feedback should be done quarterly as recommended by the guideline.
- Budget for social support(food and transport provision) for eligible patients should be availed by directing resource from different funders.

For Addis Ababa Health Bureau:

- The program-specific integrated supportive supervision with timely written feedback should be done quarterly as recommended by the guideline
- On-job training sessions and short seminars should be prepared for the staff.

For the SPSH:

- The interruptions of the reagent supply should be managed by applying the new FMOH strategy.
- Clean water for the MDR-TB ward should be availed by providing a water tanker for the ward.
- The staff rotation problem should be managed by recruiting health care professionals dedicated to the MDR-TB ward only.

For the MDR-TB case team:

- The recording and documentation of the patient individual card should be improved by recruiting more health information professionals.
- Attention should be given for counseling of the patients on adherence of the treatment by collaborating with TFCs and staff training on counseling.
- The necessary physical examination including visual acuity and color test and BMI should be done consistently.
- The post-treatment follows up should be improved by using different communication technique like using phone to communicate with patients who completed their treatment.

Chapter Nine: Meta-Evaluation

A summative meta-evaluation was conducted by using the four standards of evaluation (utility, propriety, feasibility, and accuracy). Daniel L. Stufflebeam's tool was adopted to perform the meta-evaluation(68). The tool has 30 sub-standards and 92 items. And, the Judgment parameter was decided to be Excellent, if >85%; V. Good, if 75-85%; Good, if 60-74%; Fair, if 45-60%; Poor, if <45%. The overall score of the evaluation is 86.9% which is excellent.

Utility standards

There are seven sub-standards and 23 items and among those 21 items are fulfilled which is 91.3% achieved of the utility standard measurements, which was excellent on the judgment parameter. Some of the activities done are the stakeholders were engaged and analyzed through the matrix and an evaluation questions were prioritized after discussing with the stakeholders and the judgment parameters were set.

Feasibility standards

Among 10 items eight were achieved the feasibility standards, which makes 80% of the feasibility items were done. Based on the judgment parameter, the feasibility arrived at very good. Appointing a competent staff, developing TOR and generating new insights are some of the activities completed,

Propriety Standards

Among 26 items of propriety standard 21 were achieved which is 80,7% and base on the judgment parameter set is very good. Some of the tasks done include issuing ethical clearance, keep the identity of the respondents confidential, having respectful and clear communication with the stakeholders.

Accuracy standards

This standard was measured by 33 items 91% of the items are achieved. Therefore, by the judgment matrix, it is excellent. The mixed-method was applied, the evaluation was able to meet its objectives, the tool was translated and pre-tested.

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Annexes

Annex 1: Information matrixes

Table 15: Information matrix for the availability of the necessary resource in St. Peter specialized hospital Addis Ababa

Evaluation Question	Availability Indicator	Source of data	Data Collection Method	Data collection tools
Are the resources required to provide MDR TB treatment services available? If not, why? If yes, how	Number of isolated MDR-TB inpatient beds as per NTG.	DR-TB unit head	Questioner/Observation	Checklist
	Number of MDR-TB OPD dedicated only for MDR-TB patients.	DR-TB unit head	Questioner /Observation	Checklist
	number of functional culture testing laboratory[1] in the vicinity of the hospital	DR-TB unit head	Questioner	Checklist
	Number of functional Audiometry at the time of the assessment.	DR-TB unit head	Questioner	Checklist
	Number of functional ECG machine at the time of assessment.	DR-TB unit head	Questioner/Observation	Checklist
	Number of a functional Chemistry machine at the time of assessment.	Head of Laboratory	Questioner/Observation	Checklist
	percentage of the necessary SLDs present for the last three months.	DR-TB unit head	Questioner/Observation	Checklist
	Percentage of standardized PPE[2] present for all MDR-TB ward staff at the time of assessment.	DR-TB unit head	Questioner/Observation	Checklist
	Number of a functional adult weight scale at the time of assessment.	DR-TB unit head	Questioner/Observation	Checklist
	Percentage of trained staff per the NTG from all staff at the time of assessment.	DR-TB unit head	Questioner/Observation	Checklist
	Number functional Gene Expert machine with all essential equipment[3] at the time of assessment.	Head of Laboratory	Questioner/Observation	Checklist
	Number of functional microscopes with all essential equipment for AFB at the time of assessment[4].	Head of Laboratory	Questioner Observation	Checklist
	Number of updated NTG present in the MDR-TB unit at the time of assessment.	DR-TB unit head	Questioner/Observation	Checklist

[1] Presence of solid and liquid culture media and laboratory equipment for LPA and other DST tests

[2] PPE includes N-95 or PPF masks for the HPs and clients, gloves for health care professionals.

[3] *Gene Xpert diagnostic system (the instrument and the computer), cartridges, Assay specific Gene Xpert cartridges, Printer, Surge protector(adaptor), triple package container.*

[4] *Functional Binocular light Microscopes, Slide, Frosted slide, Slide box, Sputum containers approved, Wire loops or sticks, Funnel, Filter paper, Staining rack, Sprit lamp/Bunsen burner, Lens tissue, Red pen Recording for positive result, Carbol fuchsine, Methyl blue 52 3% acid alcohol, Oil immersion, Forceps for holding slide and fixing, Alarm clock 56 5% phenol or 10% Sodium hypo chloride.*

	Number of Visual acuity test equipment present at the time of assessment.	DR-TB unit head	Questioner /Observation	Checklist
	Number of RUTF present as per the number of undernourished cases.	DR-TB unit head	Questioner /Observation	Checklist
	Number of isolated MDR-TB inpatient beds as per NTG.	DR-TB unit head	Questioner /Observation	Checklist
	Number of MDR-TB OPD dedicated only for MDR-TB patients.	DR-TB unit head	Questioner /Observation	Checklist
	number of functional culture testing laboratory[1] in the vicinity of the hospital	DR-TB unit head	Questioner /Observation	
	Number of functional Audiometry at the time of the assessment.	DR-TB unit head	Questioner /Observation	
	Number of functional ECG machine at the time of assessment.	DR-TB unit head	Questioner /Observation	
	Number of a functional Chemistry machine at the time of assessment.	DR-TB unit head	Questioner /Observation	
	percentage of the necessary SLDs present for the last three months.	DR-TB unit head	Questioner /Observation	Checklist

[1] Presence of solid and liquid culture media and laboratory equipment for LPA and other DST tests

Table 16: Information matrix for compliance TB DOT PLUS service providers to national TB guideline in St. Peter specialized hospital

Evaluation question	Indicator	Numerator and denominator for compliance indicators	Data source	Data collection method	Data collection tool
Is the treatment service implemented according to MDR TB national guidelines? If not, why?	The Proportion of patients whose baseline BMI is measured.	Number of patients enrolled in DOT PLUS service from whose BMI were measured Total number of MDR-TB patients enrolled in DOT PLUS service from March 1 2018 to September 30 2019	Document/	Document review	Checklist
	The Proportion of patients where all baseline[22] physical examinations were done.	Number of patients where all baseline physical examinations were done from March 1 2018 to September 30 2019 Total number of MDR-TB patients enrolled in DOT PLUS service from March 1 2018 to September 30 2019	Document	Document review	Checklist
	The Proportion of patients where all follow up physical examinations were done at the end of 6 months.	Number of patients where all follow up physical examinations were done at the end of 6 months. Total number of MDR-TB patients enrolled in DOT PLUS service from March 1 2018 to September 30 2019	Document	Document review	Checklist
	The proportion of patients whose SLD-PLA screening is done	Number of patients whose SLD-PLA screening is done from Total number of MDR-TB patients enrolled in DOT PLUS service from March 1 2018 to September 30 2019	Document	Document review	Checklist
		Number of HIV co-infected patients where additional lab tests were done from March 1 2018 to September 30 2019	Document	Document review	Checklist

[22] *Baseline means at the time of the diagnosis.*

Proportion of HIV co-infected patients where additional lab tests are done	Total number of HIV co-infected patients were enrolled in DOT PLUS service from March 1 2018 to September 30 2019	Document	Document review	Checklist
The proportion of MDR-TB patients who enrolled in a correct dose of treatment.	Number of MDR-TB patients who enrolled in a correct dose of treatment on intensive phase from March 1 2018 to September 30 2019 Total number of TB patients enrolled in DOT PLUS intensive phase from March 1 2018 to September 30 2019	Document/	Document review	Checklist
The proportion of MDR-TB patients who enrolled in the correct treatment regimen.	Number of MDR-TB patients who enrolled in a correct treatment regimen from March 1 2018 to September 30 2019 Total number of MDR-TB patients enrolled in DOT PLUS service from March 1 2018 to September 30 2019.	Document	Document review /observation	Checklist
The Proportion of patients where all routine blood tests were done at the end of 6 month	The number of patients where all routine blood tests were done at the end of 6 month from March 1 2018 to September 30 2019. Total number of MDR-TB patients enrolled in DOT PLUS service from March 1 2018 to September 30 2019.			
The Number of complete reports reported about adverse drug events of the patient under chemotherapy.	Number of complete reports reported about adverse drug events of the patient under chemotherapy. Total number of expected reports from March 1 2018 to September 30 2019	Document	Document review	Checklist
The proportion of bacteriologically confirmed patients for	The proportion of bacteriologically confirmed patients for whom sputum culture follow up performed at the end of 6 months of therapy from	Document	Document review	Checklist

	whom sputum culture follow up performed at the end of 6 months of therapy.	Total number of bacteriologically confirmed MDR-TB patients enrolled in DOT PLUS service from March 1 2018 to September 30 2019.			
	The proportion of MDR-TB patients who were economically supported.	# of MDR-TB patients who were economically supported March 1 2018 to September 30 2019.	Document	Document review	Checklist
		Total number of eligible MDR-TB patients March 1 2018 to September 30 2019			
	The proportion of patients who received post-treatment monitoring	Number of patients who received post-treatment monitoring for 1 year after successfully completed their treatment from March 1 2018 to September 30 2019	Document	Document review	Checklist
		Total number of patients who successfully completed their treatment from March 1 2018 to September 30 2019			
	The proportion of complete reports reported timely to FMOH.	Number of complete reports reported timely to FMOH from the hospital	Document	Document review	Checklist
		Total expected number of reports to be reported to FMOH 2012 EFY.			
	The proportion of MDR-TB patients counseled during TB DOT service	The number of MDR-TB patients counseled during TB DOT service at a time of observation.	Document	Document review	Checklist
		Total number of MDR-TB patients counseled during TB DOT service at a time of observation.			
	The proportion of MDR-TB patients observed while swallowing the drugs.	Number of MDR-TB patients observed while swallowing the drugs at a time of observation	Document	Document review	Checklist
		Total number of TB patient enrolled in DOT service at a time of data collection			
	The proportion of MDR-TB patients whose nutritional status managed accordingly.	The number of MDR-TB patients whose nutritional status screened from March 1 2018 to September 30 2019.	Document	Document review	Checklist
		Total number of TB patient enrolled and diagnosed with malnutrition from March 1 2018 to September 30 2019			

	The proportion of patients who were asked if they develop a new symptom	The number of patients who were asked if they develop a new symptom at the time of observation. Total number of patients treated at the time of observation.	Document	Document review	Checklist

Table 17 Information Matrix for the satisfaction of patients from MDR-TB Treatment service in St. Peter specialized hospital Addis Ababa

Evaluation Question	Indicator	Formula	Source of data	Data collection Method	Data collection tools
Are the clients utilizing MDR TB care in St Peter specialized hospital, Addis Ababa? satisfied with MDR TB treatment services provided to them? If not, why?	Percentage satisfaction mean the scale of MDR-TB patients satisfied with the in-patient service of the SPSH.	(MDR-TB patients satisfied with the in-patient service of the SPSH score -potential minimum score)*100 Potential maximum score(5)-potential minimum score(1)	MDR-TB patients	Interview	Questioner
	Percentage satisfaction mean the scale of MDR-TB patients satisfied the progress of their treatment	(MDR-TB patients satisfied the progress of their treatment score -potential minimum score)*100 Potential maximum score(5)-potential minimum score(1)	MDR-TB patients	Interview	Questioner
	Percentage satisfaction mean scale of MDR-TB patients satisfied with the convenience of DR-TB unit working hours.	(MDR-TB patients satisfied with the convenience of DR-TB unit working hours score -potential minimum score)*100 Potential maximum score(5)-potential minimum score(1)	MDR-TB patients	Interview	Questioner
	Percentage satisfaction mean the scale of MDR-TB patients satisfied with the time spent in the waiting room	(MDR-TB patients satisfied with the time spent in the waiting room score -potential minimum score)*100 Potential maximum score(5)-potential minimum score(1)	MDR-TB patients	Interview	Questioner

	Percentage satisfaction mean the scale of MDR-TB patients satisfied with the competence/knowledge of the providers of SPSH.	(MDR-TB patients satisfied with the competence/knowledge of the providers of SPSH score -potential minimum score)*100 Potential maximum score(5)-potential minimum score(1)	MDR-TB patients	Interview	Questioner
	Percentage satisfaction mean the scale of MDR-TB patients satisfied with the adequacy of counseling	(MDR-TB patients satisfied with the adequacy of counseling score -potential minimum score)*100 Potential maximum score(5)-potential minimum score(1)	MDR-TB patients	Interview	Questioner
	Percentage satisfaction mean the scale of MDR-TB patients satisfied with food support	(MDR-TB patients satisfied with the food support score -potential minimum score)*100 Potential maximum score(5)-potential minimum score(1)	MDR-TB patients	Interview	Questioner
	Percentage satisfaction mean the scale of MDR-TB patients satisfied with the transport payment support	(MDR-TB patients satisfied with transport payment support score -potential minimum score)*100 Potential maximum score(5)-potential minimum score(1)	MDR-TB patients	Interview	Questioner
	Percentage satisfaction mean the scale of MDR-TB patients satisfied with the overall quality of service	(MDR-TB patients satisfied with overall quality of service score -potential minimum score)*100 Potential maximum score(5)-potential minimum score(1)	MDR-TB patients	Interview	Questioner

Table 18: information Matrix of MDR-TB treatment Outcome of St. Peter specialized hospital Addis Ababa, 2020

Evaluation question	Indicator	Numerator and denominator for MDR-TB TB treatment Outcome indicators	Data source	Data collection method	Data collection tool
	Sputum conversion rate of new bacteriologically confirmed cases at the end of the intensive phase of the treatment	# of bacteriologically confirmed new DR-TB cases registered in a specified period that was culture-negative at the end of the Intensive phase of treatment	Document	Document review	Checklist
		Total number of new smear-positive pulmonary TB cases registered for treatment in the same period			
	Sputum conversion rate of previously treated bacteriologically confirmed cases at the end of the intensive phase of the treatment	# of bacteriologically confirmed previously treated DR-TB cases registered in a specified period that was culture-negative at the end of the Intensive phase of treatment from	Document	Document review	Checklist
		Total number of previously treated bacteriologically confirmed cases registered for treatment in the same period			

Annex 2: Relevance matrix of indicators

Table 19:Relevance matrix of indicators that was used in quality evaluation in St. Peter specialized hospital,2020

Indicator	Availability	Compliance	Satisfaction	Clinical Outcome
Availability indicators				
Number of MDR-TB OPD dedicated only for MDR-TB patients.	RRR	RRR	RR	RR
number of functional culture testing laboratory[23] in the vicinity of the hospital	RR	RR	R	RR
Number of functional Audiometry at the time of the assessment.	RRR	RRR	RRR	RR
Number of functional ECG machine at the time of assessment.	RRR	RRR	RR	RR
Number of a functional Chemistry machine at the time of assessment.	RRR	RR	RR	R
percentage of the necessary SLDs present for the last three months.	RRR	RR	RR	R
Percentage of standardized PPE[24] present for all MDR-TB ward staff at the time of assessment.	RRR	RR	RR	R
Number of a functional adult weight scale at the time of assessment.	RRR	RR	R	RR
Percentage of trained staff per the NTG from all staff at the time of assessment.	RRR	RRR	RRR	RR
Number functional Gene Expert machine with all essential equipment[25] at the time of assessment.	RRR	RR R	RRR	RR
Number of functional microscopes with all essential equipment for AFB at the time of assessment[26].	RRR	RR	R	RR
Number of updated NTG present in the MDR-TB unit at the time of assessment.	RRR	RRR	RRR	R
Number of Visual acuity test equipment present at the time of assessment.	RR	R	R	R

[23] Presence of solid and liquid culture media and laboratory equipment for LPA and other DST tests

[24] PPE includes N-95 or PPF masks for the HPs and clients, gloves for health care professionals.

[25] *Gene Xpert diagnostic system (the instrument and the computer), cartridges, Assay specific Gene Xpert cartridges, Printer, Surge protector(adaptor), triple package container.*

[26] *Functional Binocular light Microscopes, Slide, Frosted slide, Slide box, Sputum containers approved, Wire loops or sticks, Funnel, Filter paper, Staining rack, Sprit lamp/Bunsen burner, Lens tissue, Red pen Recording for positive result, Carbol fuchsine, Methyl blue 52 3% acid alcohol, Oil immersion, Forceps for holding slide and fixing, Alarm clock 56 5% phenol or 10% Sodium hypo chloride*.

Number of RUTF present as per the number of undernourished cases.	RRR	RRR	RRR	RR
Compliance indicators				
The Proportion of patients whose baseline BMI is measured.	RR	RRR	RR	R
The Proportion of patients where all baseline[27] physical examinations were done.	RRR	RRR	RRR	R
The Proportion of patients where all follow up physical examinations were done at the end of 6 months.	RRR	RRR	RRR	RRR
The Proportion of patients where all routine blood tests were done at the end of 6 month	RR	RR	RR	RR
The Proportion of patients whose SLD-DST screening is done	RR	RRR	RRR	RR
The Proportion of HIV comorbid patients where additional lab tests are done	R	RRR	RR	RR
The Proportion of MDR-TB patients who enrolled in a correct dose of treatment.	R	RRR	R	RR
The Proportion of MDR-TB patients who were enrolled in the correct treatment regimen.	RR	RRR	R	RR
The proportion of MDR-TB patients' monthly culture was performed at the end of 6 months.	RR	RRR	R	R
The Number of complete reports reported about adverse drug events of the patient under chemotherapy.	R	RRR	R	RR
The Proportion of patients who received the post-treatment monitoring in the hospital.	R	RRR	RR	RR
The proportion of bacteriologically confirmed patients for whom sputum culture follow up performed at the end of 6 months of therapy.	R	RR	R	R
The number of complete reports reported timely to FMOH	R	RR	R	R
The Proportion of MDR-TB patients counseled during MDR-TB DOT Plus service	R	RRR	RR	R
The proportion of MDR-TB patients observed while swallowing the drugs.	R	RRR	R	RR
The proportion of MDR-TB patients whose malnutrition was managed	R	RRR	R	RR
The proportion of patients who were asked if they develop a new symptom	R	RRR	R	RR
Satisfaction				

[27] *Baseline means at the time of the diagnosis.*

Percentage satisfaction mean the scale of MDR-TB patients satisfied with the in-patient service of the SPSH.	RR	R	RRR	R
Percentage satisfaction mean the scale of MDR-TB patients satisfied the progress of their treatment	RR	R	RRR	RR
Percentage satisfaction mean the scale of MDR-TB patients satisfied with the convenience of DR-TB unit working hours	RR	R	RR	RR
Percentage satisfaction mean the scale of MDR-TB patients satisfied with the time spent in the waiting room	R	RR	RRR	R
Percentage satisfaction mean the scale of MDR-TB patients satisfied with the competence/knowledge of the providers of SPSH.	RR	R	RRR	R
Percentage satisfaction mean the scale of MDR-TB patients satisfied with the adequacy of counseling	RR	R	RR	R
Percentage satisfaction mean the scale of MDR-TB patients satisfied with food support	RR	R	RRR	RR
Percentage satisfaction mean the scale of MDR-TB patients satisfied with the transport payment support	R	RR	RRR	R
Percentage satisfaction mean the scale of MDR-TB patients satisfied with the overall quality of service	R	RR	RRR	RR
Clinical Outcome				
Sputum conversion rate of new bacteriologically confirmed cases at the end of the intensive phase of the treatment	RR	R	RR	RRR
Sputum conversion rate of previously treated bacteriologically confirmed cases at the end of the intensive phase of the treatment	R	RR	RR	RRR

Annex 4: Data collection tools

Data extraction check list for TB patient charts/document review

Name of HC_____

Name of data collector_____ sig.

_____

Name of supervisor _____ sig.

_____

Instruction: Mark (√) if the following evidences were recorded in TB patient chart, and mark (X) if not and write what is written on the document for which write is in the bracket.

Variables to measure	baseline	W2	M1	M2	M3	M4	M5	M6	ON INJ.	Till End of Tx	End of Tx	Post Tx 6 month
	Clinical evaluation											
Vital signs												
Peripheral neuropathy screen												
Audiometry												
Visual acuity and color vision screen												
Outcome consultation												
Assessment/follow-up of AEs												
BMI screening												
Managed accordingly												
Contact Hx done?												
	Bacteriological Testing											
Smear												
Culture												
Culture-based SL DST (smear pos)												
	Laboratory/Clinical/Radiology testing											
ECG												
Full Blood Count												
Urea, creatinine												
Serum electrolytes												
Liver function tests												

TSH (every 3 months)												
Hepatitis Bs Antigen												
Hepatitis C Antibody												
HbA1c or FBS												

Interview for MDR-TB patients

Consent forms for MDR-TB patients at St. Peter Hospital,

Dear sir/ madam My name is _____ I am a member of an evaluation team of quality evaluation of MDR-TB DOT PLUS treatment services in St. Peter specialized hospital in Addis Ababa. It is believed that strongly implemented TB DOT PLUS service increases clients' satisfaction, which contributes to increase in good treatment outcomes. The purpose of this study is to evaluate the quality of the process of MDR-TB DOT PLUS service provided in St. Peter specialized hospital and the level of satisfaction of MDR-TB patients, and finally to give an important comment that will help to strengthen and improve quality of service. To do this, your information is very important. I would like to ask you a few questions about your visit to the St. Peter specialized hospital to find out your experience today. I would be very grateful if you could spend a few minutes answering questions related to the service. your name will not be recorded and all the information you give was kept strictly confidential. Your participation is voluntary and you are not forced to answer any questions you don't want. But your honest participation will contribute to generate information that can be used to improve the quality of implementation of TB DOT PLUS service. Do I have your permission to continue? Yes _____ No_____

Name of data collector_____ sig. ____
Name of supervisor _____sig._____
Date _____

S.N	Questions	Response
Socio-Demographic and General Characteristics of Patient		
1	Gender of respondent	1.Male 2. Female
2	Age	_____

3	Marital status	1. Married 4. Divorced 2. Single (Never married) 5. Widowed 3. Separated
4	Family size	_____
5	Residence	1. Urban 2. Rural
6	education level	1. Diploma and above 4. Primary school 2. Preparatory 5. No formal education 3. Secondary school
7	Occupation	1. Permanent employee 4. Unemployed 2. Self-employee 5. Pensioner 3. Temporary employee
8	Religion	1. Orthodox 2. Protestant 3. Catholic 4. Muslim 5. No religion 6. Other
9	Type of DR-TB	1. Pulmonary positive TB 2. Pulmonary Negative TB 3. Extra Pulmonary TB
10	Treatment category from card	1. New 4. Return after lost follow up 2. Relapse 5. Transfer in 3. Treatment after Failure 6. Other (specify_____
11	When did you start TB treatment	(DD/MM/YYYY) _____
12	In which department are you getting your treatment?	1. In-patient 2.OPD
13	Do you have TB symptoms now	1.Yes, 2. No
14	Total planned treatment duration	1. 9-11 months 2. 18-24 months 3. Other (specify)_____
15	Currently how you are taking your TB drugs	1. Daily 2. Weekly 3. Monthly 4. Other
16	Did you expect to come and collect the drugs every ------for this much time?	1.Yes, 2. No
17	Do you think that you and HCPs have good communication?	1.Yes, 2. No

Satisfaction with the services provided

The following are statements about different characteristics that the client satisfies with. Please answer according to your agreement in the statement.

Number from 1-5 represents your satisfaction level with each statement, and rate as follow based on your agreement:5 =Very satisfied 4 =satisfied 3= Neutral 2 =Dissatisfied 1 =Very dissatisfied

Table 20: Patient Satisfaction Questions

S.N	Client satisfaction item	v. satisfied	Satisfied	Neutral	Dissatisfied	v. dissatisfied
1	How satisfied are you with the availability of necessary drugs when needed?					
2	How satisfied are you with the availability of laboratory service when needed?					
3	How satisfied are you with the presence of DR-TB treatment service providers at work time/home/ward?					
4	How satisfied are you with the in-patient service of the hospital for TB treatment? (IPD)					
5	How satisfied are you with the outpatient service of the hospital for TB treatment? (OPD)					
6	How satisfied are you with the convenience of DR-TB unit work hours?					
7	How satisfied are you with time spent in the waiting room?					
8	How satisfied are you with the friendliness/courtesy of the providers?					
9	How satisfied are you with the attention and respect of providers to your privacy?					

10	How satisfied are you with the perceived competence/knowledge of the providers?					
11	How satisfied are you with the adequacy of explanation about treatment?					
12	How satisfied are you with the adequacy of transportation and housing fee? (if eligible)					
13	How satisfied are you with the adequacy of the food basket provided? (if eligible)					

በቅ/ጴጥሮስ ሆስፒታል መድሀኒት ለተላመደ ቲቢ ህክምና አገልገሎት አሰጣጥ ላይ ለሚደረግ ጥናት የተዘጋጀ መጠይቅ

የሚስጥር አጠባበቅ ስምምነት

ጤና ይስጥልኝ እኔ----------እባላለሁ::የምሰራዉጅማዩኒቨርስቲጤናሳይንስኮሌጅድህረ-ምረቃተማሪለሆነውየጥናትቡድንአባልሆኜእንደጊዜያዊመረጃ(ዲታ) ሰብሳቢበመሆንነው:: በቀጥታየባለሙያክትትልስርየሚሰጥመድሀኒትንየተላመደቲቢአገልግሎትአሰጣጥየተገልጋዩንእርካታበመጨመርተገልጋዩመድሀኒቱንበአገባቡእንዲጭርስናእንዲፈወስየራሱአስትዋጽኦአለውተብሎይታመናል::
የጥናቱአላማየቅ/ጴጥሮስሆስፒታልመድሀኒትለተላመደቲቢህክምናአገልገሎትአሰጣጥጥራትናየተገልጋዮችእርካታላይየሚደረግ ጥናትሲሆን፣ለዚሁበአገለግሎትአሰጣጥጥራትላይያሉክፍተቶችንበመለየትየመፍትሄአቅጣጫመጠቆምይሆናል::
ይህንንለማድረግየእርስዎመሳተፍየማይትካሚናአለው::
አገለግሎቱንለማግኘትሆስፒታሉውስጥስላገኙትአገልግሎትየተወሰኑጥያቄዎችንለጥቂትደቂቃዎችታግሰውእንዲመልሱልኝእጠ ይቆታለው::ጥያቄዎቼንእንዲመልሱልኝእጠይቆታለው::ስምዎትአይመዘገብም፣
የሚሰጡኝምመረጃሚስጥራዊነቱየተጠበቀነው::
በጥናቱሊይየሚሳተፈትበሙሉፍላጎትዎሲሆንበሙሉምሆነበከፊልያለመሳተፍመብትዎየተጠበቀነዉ::
መመለስየማይፈልጉትንጥያቄአለመመለስመብትዎነው::
ጥናቱሊይያለመሳተፍዉሳነዎየተከበረከመሆኑምበላይየጤናአገልግሎትአጠቃቀሞትላይምንምዓይነትችግርአይከሰትም::
ነገርግንየእርሶትብብርመድሀኒትየተላመደየቲቢአገልገእሎቱንእንድናሻሻልይረዳናል::

አሁንበጥናቱላይለመሳተፍተስማምተዋል?

አዎን---------- አይደለም---------- ፈቃደኛካልሆኑዉሳኔያቸዉንአክብረህ (ሽ)

በማመስገንወደቀጣዩተገልጋይሂድ(ጂ)

የተስማሙከሆነቃለመጠይቁንቀጥል(ይ)

ቃለመጠይቁንያደረገ(ች)ዉስም---------- ፉርማ-------- ቀን----------

የተቆጣጣሪውስም---------- ፉርማ-------- ቀን----------

ተ.ቁ	ጥያቄ	አማራጭመልስ
ክፍልአንድ፤-ማህበራዊናስነ-ህዝባዊመረጃዎች		
001	ፆታ	1. ወንድ 2. ሴት
2	እድሜ	_____
3	የትዲርሁኔታ	4. ያገባ 4. የተፋቱ 5. ያላገባ5. ባል/ሚስትየሞተበት/የሞተባት 6. የተለያዩ
4	የቤተሰብብዛት	_____
5	የመኖሪያቦታ	1.አዲስአበባ 2. ከአዲስአበባውጪ
6	የመጨረሻውየትምህርትደረጃ	1.ዲፕሎማናከዚያበላይ 2.የመሰናዶት/ቤት3. .ሁለትኛደረጃት/ቤት 4. የመጀምሪያደረጃት/ቤት 5. መደበኛትምህርትያልተማረ
7	የስራሁኔታ	4. ቋሚሰራተኛ4. ስራየሌለው 5. የግልስራ5. ጡረተኛ 6. ጊዜያዊሰራተኛ
8	ሀይማኖት	1. ኦርቶዶክስ 2. ፕሮቴስታንት 3. ካቶሊክ4.እስልምና 5. ሁይማኖትየሌለው6. ሌላካለይጥቀሱ
9	መድሀኒትየተላመደይቲቢአይነት	4. በአክታምርመራየተረጋገጠየሳንባቲቢ 5. በአክታምርመራየተረጋገጠየሳንባቲቢ 6. ከሳንባውጪሌላየሰውነትክፍልላይያለቲቢ
10	Treatment category from card (ከካርድሙላ)	4. New 4. Return after lost follow up 5. Relapse 5. Transfer in 6. Treatment after Failure 6. Other (specify_____
11	When did you start TB treatment (ከካርድሙላ)	(DD/MM/YYYY) _____
12	የህክምና ክትትልህ ምን ይመስላል?	1 ተኝቶ ታካሚ(inpatient) 2. ተመላላሽ ታካሚ (OPD)
13	አሁንየቲቢበሽታምልክቶችአሉብህ(ሽ)?	1.አለ 2. የለም
14	አጠቃላይህክምናውአንትጊዜይፈጃል	1. 9-11 ወራት2. 18-24 ወራት 3.ሌላካለይጥቀሱ_____
15	አሁንመድሀኒትህንመቼመቼነውእየወሰድክያለሽ (ህ)ው (ለተመላላሽታካሚብቻ)	1. በየቀኑ 2. በየሳምንቱ 3.በየወሩ 4. ሌላካለይጥቀሱ.....
16	ለምንያህልጊዜነውእየተመላለስክመውሰድየሚጠበቅብህ?	..... ወራት
17	ከሚከታተልህጤናባለሙያጋርተግባቦት(communication)አላችሁ?	1.አለ 2. የለም

የአገልግሎትአርካታዳሰሳ

የሚከትሉትጥያቄዎችየተለያዩየቲቢህክምናያገልገሎትዘርፎችላይየተገልጋይንአርካታየሚዳሰሱናቸው።

እባክዎትንየሚስማሙበትንየእርካታደረጃመሰረትይመልሱ።

ከቁጥር 1-የምወክለውበየአንዳንዱአረፍተነገርላይያሎትንየእርካታደረጃነው, ባገልገሎቱባሉትየርካታደረጃመሰረት:5 =በጣምእስማማልወ4 =እስማማለወ3= አስትያየትየለኝም 2 =አልስማማምም1 =በጣምአልስማማም

ተ.ቁ	አጠቃላይየእርካታመጠይቅ	በጣምአልስማማም	አልስማማም	አስተያየትየለኝም	እስማማለው	በጣምእስማማለው
1	መድህኒትየተላመድቲቢመድሀኒቶችንባስፈልገኝጊዜሁሉአገኛለው					
2	የላቦራቶሪምርመራዎችንባስፈለግኝጊዜሁሉአገኛለው					
3	በመደበኛየስራሰአትበማገኘውአገልግሎትእረክቻለው					
4	መድህኒትየተላመደየቲቢህክምናእዚህሆስፒታልበመኖሩደስተኛነኝ					
5	በተኝቶየህክምናክፍል(ተኝተውለሚታከሙ)በሚስጠኝአገልግሎትደስተኛነኝ					
6	በተመላላሽየህክምናክፍል(ተመላለሰውለሚታከሙ)በሚስጠኝአገልግሎትደስተኛነኝ					
7	አገልግሎቱየሚሰጥበትሰአትመጥቼለመገልገልምቹነው					
8	አገልግሎትከማግኘቴበፊትበጤናተቋሙየሚያሳልፈውየቆይታጊዜበኔዘንድተቀባይነትአለው					
9	የሆስፒታሉባለሙያዎችያላቸውቀረቤታየውዳጅነትነው					
10	የጤናባለሙያዎቹበጥንቃቄናበምክክርወቅትለብቻበተለየክፍልያስተናግዱኛል					
11	በጤናባለሙያዎችእውቅትናብቃትደስተኛነኝ					
12	ሰለህክምናውሂደትባለሙያዎቹየሰጡኝማብራሪያበቂነው					
13	ለቤትኪራይናለትራንስፖርትየሚስጠኝድጎማበቂነው					
14	የሚቀርብልኝየምግብድጋፍበቂነው					

Inventory checklists to assess availability of resource for providing MDR-TB DOT PLUS

Name of data collector_____ sig._____

Name of supervisor _____ sig. _____ date_____

NOTE: check for expire date of reagents and drugs, describe appropriately

A. Check list to assess availability of resource for providing MDR-TB DOT PLUS

Item No.		Yes	No	
1	Did the Hospital have a full time trained MDR-TB DOT provider?			
2	Is there an isolated MD-TB ward?			
3	Is the Hospital having cough clinic?			
4	Is the Hospital having an isolated DR-TB laboratory set up?			
5	Is the standard MDR-TB unit available?			
6	Is Hospital having functional adult weighing scales for DOT PLUS service?			
7	Is the hospital having functional pediatric weighing scales for DOT PLUS service?			
8	Is laboratory unit having functional microscopy?			
9	Is hospital having essential laboratory equipment? *			
10	Is the hospital having the adequate amount of AFB reagents?			
11	Is the hospital TB unit having standard DR-TB unit register?			
12	Is Hospital laboratory units having laboratory AFB registration book?			
13	Is TB DOT providers received training within one year?			
14	Is Hospital has updated Guidelines for MDR-TB diagnosis and treatment?			
15	Is the hospital having health education (EIC) materials?			
16	Is this hospital conduct IQA?			
17	Essential drugs for adverse effect management			
18	Surgical masks are available for presumptive and DR-TB patients			
19	N-95 and FFP2 respirators are readily available for staff?			
20	Separate room for sputum collection is available?			
21	Separate waiting area exists in the facility to isolate potentially infectious individuals?			
22	Flowcharts or algorithms on DR-TB screening			

23	Flowcharts or algorithms on DR-TB diagnosis and treatment regimens					
24	Is there Report copy sent to FMOH					
25	Is there written feedback after supportive supervision for the last 6 months?					
			Yes	No	If yes quantity in Number	Remark
2	Is the hospital having the adequate amount of adult doses of essential TB drugs?					
2.1	Group A	Bed aquiline (Bdq)				
		Levofloxacin (Lfx)				
		Moxifloxacin (Mfx)				
		Linezolid (Lzd)				
2.2	Group B	Clofazimine (Cfz),				
		Cycloserine (Cs)				
2.3	Group C:	Capreomycin (Cm)				
		Kanamycin (Km)				
		Amikacin (Amk)				
		Delamanid (Dlm)				
		Protionamide (Pto) or Ethionamide (Eto)				
2.4		Isoniazid				
		Ethambutol				
		Pyrazinamide				
		Streptomycin				
3	Is the hospital having the adequate number of pediatric doses of essential TB drugs?					
3.1		Bed aquiline (Bdq)				
3.2		Levofloxacin (Lfx)				
3.3		Ethionamide (Eto)				
3.4		Linezolid (Lzd)				
3.5		Clofazimine (Cfz),				
3.6		Cycloserine (Cs)				
3.7		Delamanid (Dlm)				
3.8		Protionamide (Pto)				
3.9		Pyridoxine (VitB6)				
4	Presence of Rapid DST Diagnostic tools	LPA Assay				
		Gene Xpert				
		Phenotypic DST				

4.1	Presence of Xpert MTB/RIF cartridge				
4.2	Presence of Liquid culture Media				
4.3	Presence of Solid culture media				
4.4	Presence of CBC Machine				
4.5	Presence of Chemistry machine				
4.6	Presence of HCG kit				
4.7	Presence of Hepatitis testing kit				
4.8	Presence of Glucosure				
4.9	Presence of X-Ray machine				
4.10	Presence of ECG machine				
4.11	Presence of Audiometry				
4.12	Presence of CD4 Machine				
4.13	Presence of HIV/AIDS testing kit				
4.14	Presence of viral load machine				
4.15	Presence of concomitant drugs like pyridoxine?				
4.16	Is there RUTF & RUSF				

** Functional Binocular light Microscopes, Slide, Frosted slide, Slide box, Sputum containers approved, Wire loops or sticks, Funnel, Filter paper, Staining rack, Sprit lamp/Bunsen burner , Lens tissue, Red pen Recording for positive result , Carbol fuchsine, Methyl blue 52 3% acid alcohol, Oil immersion, Forceps for holding slide and fixing , Alarm clock 56 5% phenol or 10% Sodium hypo chloride*

Provider-patient interaction observation checklist

Name of data collector _____sig._____

Name of supervisor _____ sig. _____

Checklist to assess compliance of DR-TB DOT PLUS care provider to national guideline

NOTE: This assessment should be completed by observing the care provider while providing TB DOT PLUS

Q. N	Compliance Checklist	Yes	NO
1.	Did the care provider greet a patient politely?		
2.	Did care providers ask patients (or caregivers, if patients are children) if they missed any days of therapy? (if ambulatory)		
3.	If they (patients/ caregivers) missed days, did care provider ask what was done (e.g., took the next day) and counsel for better adherence (If no problems, ask HCW how they would counsel patient)		
4.	Did the provider stress very well about the problem of defaulting& explain the method they can be easily traced?		
5.	Did care providers ask patients about any new symptoms (possible side effects to treatment)?		
6.	While discussing with the patient, did the provider use clear language that patient understand simply...if possible local language		
7.	Did the provider conduct Audiometry?		
8.	Did the provider check visual acuity?		
9.	Did the provider do a nutritional assessment (MUAC or BMI)		
10.	Did the provider screen for peripheral neuropathy?		
11.	If the new case, did the provider conduct all lab tests as per guideline? *		
12.	Did the provider put the patient in a correct regimen?		
13.	Did the provider put the patient in a correct dose?		
14.	Did the provider assess the patient for adverse drug events?		
15.	Did the provider perform SL-DST?		
16.	Did the provider perform Additional tests for HIV co-morbid patients?		
17.	Did the provider properly counsel on drug adherence?		
18.	Did the social worker support the patient socioeconomically (if eligible)		
19.	Did the provider order routine lab tests? **		
20.	Before the treatment, did the provider measure patient weight?		
21.	Did the health worker provide the correct drug based on the weight of the patient?		
22.	Did the care provider observe the patient while swallowing the drugs?		
23.	Did the care provider remind the patient of the schedule of the next sputum examination?		
24.	Did the provider order routine checkup laboratory diagnostic methods?		

25.	Did the provider let the patient ask any questions the patient may have?		
26.	Did the provider respond to the patient's questions?		
27.	Did the health worker record on the unit register immediately after the Consultation of every patient?		

*Baseline lab tests include CBC, RFT, LFT, serum electrolyte, ECG, TFT, Culture-based FL & SL DST, RBS, HCG test, Hepatitis B&C test, HIV test, chest-Xray, Gene Xpert, smear test

**Routine lab tests include CBC, RFT, LFT, serum electrolyte, ECG, TFT, chest-Xray, Gene Xpert, Smear test

Compliance and Interim outcome extraction checklist from the Register

s.no	Variables	Yes	NO	Remark
1.	Did the provider conduct Audiometry?			
2.	Did the provider check visual acuity?			
3.	Did the provider do a nutritional assessment (MUAC or BMI)			
4.	Did the provider screen for peripheral neuropathy?			
5.	Did the provider perform SL-DST?			
6.	Did the provider perform Additional tests for HIV co-morbid patients?			
7.	Did the provider put the patient in a correct regimen?			
8.	Did the provider put the patient in a correct dose?			
9.	Did the provider assess the patient for adverse drug events?			
10.	Did the provider perform post-treatment monitoring for patients who finished their treatment and declared cured or complete for the last 1 year?			
11.	Is there bacteriologically confirmed new DR-TB cases who were culture-negative but reverse back to culture Positive (2x consecutive) during the continuous phase of treatment			
12.	Is there bacteriologically confirmed previously DR-TB cases who were culture-negative but reverse back to culture Positive (2x consecutive) during the continuous phase of treatment			
13.	Is there MDR-TB newly diagnosed patients who were reversed back into culture-positive result during the treatment period.			
14.	Is there MDR-TB previously diagnosed patients who were reversed back into culture-positive result?			

Interview Guide for Qualitative Method Interview guide to Addis Ababa city TB DOT PLUS program expert

Consent forms

Dear sir/ madam, my name is _____ I came from Jimma University. I am a conducting quality evaluation of MDR-TB DOT PLUS service. The purpose of the study is to find ways of improving the quality of implementation of MDR-TB DOT PLUS service. I am interested to know your experiences so far in MDR-TB DOT PLUS services. May I ask you some questions about this? Please be assured that this discussion is strictly confidential and your name will not be recorded. Also, you are not forced to answer any question you don't want to, and you may withdraw from the interview at any time.

Do I have your permission to continue? Yes ___No___

Name and signature of the data collector: _____start time _____end time_____

Date of data collection __ /__/ __Name and signature of the supervisor: _____

Age of respondent_____ sex_____

Profession _____ experience in national TB program in this town_____

1. Is there any problem related to TB DOT PLUS program? If yes, what are the problems related to TB DOT PLUS program? What are the likelihood solutions? _____

2. In your opinion, how could compliance of MDR-TB DOT providers to national guideline improved? What else? _____

_____

3. Describe the availability of trained health workers involved in MDR-TB DOT PLUS treatment in this hospital? _____
4. Describe the adequacy of drugs and reagents? Is there an occasion of interruption and why? Which items? What measures were taken for interruption or shortage and your suggestion to improve? _____

Thank you

Interview guide to heads of MDR-TB unit of the Hospital

Consent forms for all TB DOT PLUS service providers at _____ hospital

Dear sir/ madam, my name is _____ I came from Jimma University. I am a conducting quality evaluation of MDR-TB DOT PLUS service. The purpose of the study is to find ways of improving the quality of implementation of MDR-TB DOT PLUS service. I am interested to know your experiences so far in providing MDR-TB DOT PLUS services. May I ask you some questions about this? Please be assured that this discussion is strictly confidential and your name will not be recorded. Also, you are not forced to answer any question you don't want to, and you may withdraw from the interview at any time.

Do I have your permission to continue? Yes _____No_____

Name and signature of the data collector: _____start time _____end time_____

Date of data collection __ /__/ __Name and signature of the supervisor: _____

Age of respondent_____ sex_____

Profession _____ experience in national TB program in this HOSPITAL_____

1. How do you assign TB DOT PLUS provider in DR-TB unit? What else?

_____

2. Have care providers receive training on DR-TB DOT PLUS within the last one year? If no why?

_____ 3. In your opinion, how could compliance of TB DOT PLUS care providers to national guideline improved?

_____

4. In your opinion how could availability of resource improved?
5. What are the general problems related to the TB DOT PLUS program? What are the likelihood solutions?
6. Describe the adequacy of drugs and reagents? Is there an occasion of interruption and why? Which items?
7. Is this hospital supervised by the TB program expert of FMOH in the last six months? If yes is that supportive?
8. Is EQA performed with in the last three months? If yes, is an adequate performance is observed? if no what is possible reason?

Thank you

Interview guide to MDR-TB DOT PLUS providers (MDR-TB focal person)

Consent forms

Consent forms for all TB DOT PLUS service providers at _____ hospital

Dear sir/ madam, my name is _____ I came from Jimma University. I am conducting implementation evaluation of TB DOT PLUS service. The purpose of the study is to find ways of improving the quality of implementation of the TB DOT PLUS service. I am interested to know your experiences so far in providing TB DOT PLUS services. May I ask you some questions about this? Please be assured that this discussion is strictly confidential and your name will not be recorded. Also, you are not forced to answer any question you don't want to, and you may withdraw from the interview at any time.

Do I have your permission to continue? Yes _____No_____

Name and signature of the data collector: _____start time _____end time_____

Date of data collection __ /__/ __Name and signature of the supervisor: _____

Age of respondent_____ sex_____

Profession _____ experience in national TB program in this HOSPITAL_____

1. How do you assign in MDR-TB unit? What else?

_____

2. Have you received training on TB DOT within the last one month? Is the training helpful? If no why?

_____

4. In your opinion, how could compliance of TB DOT PLUS care providers to national guideline improved?

_____

5. In your opinion how could availability of resource improved?

6.What are the general problems related to TB DOT PLUS program? What are the likelihood solutions?

7. Describe the adequacy of drugs and reagents? Is there an occasion of interruption and why?

Which items?

Thank you

Annex 5: Meta-Evaluation Judgement checklist

Checklist for Judging Evaluation Designs and Reports

Title of Evaluation document: Evaluation of Quality of Multi-Drug Resistant Tuberculosis Treatment services in St, Peter specialized hospital Addis Ababa, Ethiopia

Name of reviewer: program stakeholders

This judgement checklist contains the four Meta evaluation standards (Utility, feasibility, propriety and accuracy) with their total 30 sub-standards. Each sub-standard also have checkpoints and a total point of 92 cheek pointes.

A. The Requirements for Utility Standard

Sub-Standards and checkpoints	Met criteria			Elaboration
	Yes (1)	No (0)	NA	
U1: Stakeholder Identification				
Does clearly identified the evaluation client	1			
Does consult potential stakeholders to identify their information needs	1			
Do arrange to involve stakeholders throughout the evaluation	1			
Are address stakeholders' evaluation needs	1			
Does the information to be provided allow necessary decisions about the program to be made?	1			
U2: Evaluator credibility				
Does the evaluator can address stakeholders' concerns?	1			
Does the evaluation plan respond to key stakeholders' concerns?	1			
Do the given stakeholders' information technical quality and practicality?	1			
Do appropriately attend stakeholders' criticisms and suggestions?	1			
U3: Information scope and selection				
Are the client's evaluation requirements understood?		0		
Assign priority to the most important stakeholders?	1			
Do the stakeholders' questions address?	1			
U4: Values identification				

Do alternative sources of values consider for interpreting findings	1			
Are a clear, defensible basis for value judgments provide	1			
Do identify pertinent customer needs	1			
Do the stakeholders' values considered?	1			
U5: Report clarity				
Do reports focus on contracted questions?	1			
Are conclusions and recommendations have support?	1			
U6: Report timeliness and Dissemination				
Are make timely interim reports to intended users?	1			
Does the presentations appropriately briefed?		0		
U7: Evaluation Impact				
Do stakeholders' use of findings encourage and support?	1			
Does make sure that reports are open, frank, and concrete?	1			
Does supplement written reports with ongoing oral communication?	1			

B. The Requirements for Feasibility Standards

Sub-Standards and checkpoints	Met criteria			Elaboratetin
	Yes (1)	No (0)	NA	
F1: Practical Procedures				
Do data burden minimize?		0		
Does competent staff appoint?	1			
Does TOR develop?	1			
F2: Political Viability				
Do bias or misapply the findings counteract attempts?	1			
Do agree on editorial and dissemination authority	1			
Does any corrupted evaluation terminate	1			

F3: Cost Effectiveness				
Does program improvement foster?	1			
Does accountability information provide?	1			
Do new insights generate?	1			
Do effective practices spread?		0		

C. The Requirements for Propriety Standards

Sub-Standards and checkpoints	Met criteria			Elaborate
	Yes (1)	No (0)	NA	
P1: Service Orientation				
Does excellent service promote?	1			
Do the evaluation's service orientation clear to stakeholders?	1			
Are program strengths to build on Identify?	1			
Are harmful practices expose?	1			
P2: Formal Agreement				
Did the evaluation receive ethical approval letter?	1			
Do confidentiality/anonymity of data formal was assured?	1			
P3: Rights of Human				
Do make clear to stakeholders that the evaluation will respect and protect the rights of human subjects?	1			
Do stakeholders inform?	1			
Are participant values understand?	1			
P4: Human Interactions				
Are relate to stakeholders in a professional manner?	1			
Does effective communication with stakeholders maintain?	1			
Does the institution's protocol follow?			0	
Are sensitive to participants' diversity values and cultures?	1			
P5: Complete and Fair Assessment				

Do give account of the evaluation's process?	1			
Do have the draft report reviewed?	1			
Is acknowledge the final report's limitations?	1			

P6: Disclosure of Findings				
Do define audiences right-to-know the finding?	1			
Are report all findings in writing?	1			
Do disclose the evaluation's limitations?	1			
Do assure that reports reach their audiences?		0		
P7: Conflict of Interest				
Are potential conflicts of interest identify		0		
Do engage independent parties to assess the evaluation		0		
Do engage uniquely qualified persons, even if they have a potential conflict of interest	1			
P8: Fiscal Responsibility				
Are specify the budget for items expense?	1			
Do assign responsibility for managing the evaluation finances?		0		
Does expenditure summary as part of evaluation report?	1			

D. The Requirements for Accuracy Standards:

Sub-Standards and checkpoints	Met criteria			Elaborate
	Yes (1)	No (0)	NA	
A1: Program Documentation				
Do collect the intended program descriptions	1			
Does describe how the program was intended to function	1			
Are discrepancies between the various descriptions' analyses	1			
A2: Context Analysis				

Do multiple sources of information use to describe the program's context?	1			
Do estimate context of program outcomes effects?	1			
A3: Described Purposes and Procedures				
Do identify points of agreement among stakeholders regarding the evaluation's purposes		0		
Does the actual evaluation procedures record	1			
A4: Defensible Information Sources				
Are variety sources of information obtain?				
Do employ a variety of data collection methods?	1			
Do define the population for each source?	1			
A5: Valid Information				
Do the evaluation focus on key questions	1			
Do the data collectors train and calibrate	1			
A6: Reliable Information				
Do the unit of analysis specify?	1			
Do levels of reliability of measuring devices acceptable?	1			
Are the consistency of scoring, categorization, and coding check and report?	1			
A7: Systematic Information				
Do establish protocols for quality control of information?	1			
Are check the accuracy of scoring and coding?	1			
Do data tables generated from computer output proofread and verify?	1			
A8: Analysis of Quantitative Information				
Are choose appropriate procedures for evaluation questions and nature of the data	1			
Do examine variability as well as central tendencies	1			
Do identify and examine outliers and verify their correctness	1			

Do identify and analyses statistical interactions	1			
A9: Analysis of Qualitative Information				
Do define the boundaries of information to be used	1			
Do choose appropriate analytic procedures and methods of summarization	1			
Do test the derived categories for reliability and validity		0		
A10: Justified Conclusions				
Do conclusions focus directly on the evaluation questions?	1			
Do reflect the evaluation findings?	1			
A11: Impartial Reporting				
Do establish and follow appropriate plans for releasing findings to all audiences?	1			
Do report perspectives of all stakeholder groups?	1			
A12: Meta-evaluation				
Do define the standards to be used judging the evaluation?	1			
Do assign responsible body for documenting and assessing the evaluation process and products?		0		
Do evaluate the instrumentation, data collection, data handling, coding, and analysis against the relevant standards?	1			
Do maintain a record of all Meta evaluation steps, information, and analyses?	1			

Annex 6 The principal component analysis Results

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.777
Bartlett's Test of Sphericity	Approx. Chi-Square	501.093
	Df	36
	Sig.	.000

Communalities		
	Initial	Extraction
happy for Inpatient service	1.000	.740
happy for progress of Tx	1.000	.778
service time is convenient	1.000	.860
happy for waiting time	1.000	.782
perceived knowledge of hp	1.000	.834
adequate explanation	1.000	.825
transport support	1.000	.847
food support	1.000	.765
overall service quality	1.000	.605
Extraction Method: Principal Component Analysis.		

Rotated Component Matrix			
	Component		
	1	2	3
transport support	.908		
happy for Inpatient service	-.857		
food support	.849		
overall service quality	.564		
service time is convenient		.914	
happy for progress of Tx		.866	.
happy for waiting time		.836	
perceived knowledge of hp			.886
adequate explanation			.847
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